



## Fake Vaccine in Children and the Protection

*Evie Fitriani*

Hang Tuah University Surabaya, Indonesia

Corresponding Author: Evie Fitriani

Email: [fitriani.evie.fe@gmail.com](mailto:fitriani.evie.fe@gmail.com)



### Article Info

#### Article history:

Received 29 September 2020

Received in revised form 20  
October 2020

Accepted 28 October 2020

#### Keywords:

Fake Vaccine

Consumer Protection

Children

### Abstract

*The development of vaccines in Indonesia is not only for adults but also for children. However, some of the vaccines for children in circulation are fake vaccines that do not provide the expected immune system. This study contains 2 problem formulations, namely: 1. Role of government. 2. Business actors' liability for losses suffered by consumers. This study used a statute approach and a conceptual approach. There are also other laws that regulate consumer protection laws regarding rights and obligations that are violated, the role of government in controlling these fake vaccines and its accountability. The result of this research is the role of government in deciding the distribution of fake vaccines in Indonesia as well as to fulfill consumer rights and business actors' responsibility for the distribution of fake vaccines and their compensation.*

## Introduction

Health development, which is basically the responsibility of the state, becomes very important because the private sector also participates in creating a product in the health sector. This community is generally referred to as consumers (Detmer et al., 2008; Wilson, 2012). However, the interests of consumers as users of a product in the form of goods and/or services are often ignored by producers. As businessman, producers only think about the amount of profit that they will get through product sales without thinking about consumer rights.

Recently, fake vaccines have been circulating in children, which has caused social anxiety. There are many requests from the middle and upper class community to ask for alternative vaccines or imported vaccines and this is the opening for fake vaccines in circulation. The fake children's vaccines are made in a non-sterile manner, not in accordance with the Regulation of the Head of BPOM Number HK. 03.1.23.10.11.084081 of 2011 concerning Criteria and Procedure for Drug Registration.

## Methods

In this study, it is related to the importance of protecting consumers of Indonesian citizens, especially children who have used fake vaccines circulating in a number of health facilities, then using the approach of national statute that applies as positive law in Indonesia. So that the formulation of the problem in legal issues can be resolved, and using a conceptual approach through existing views and doctrines, it can be concluded that a legal discovery is based on developing ideas. The statute approach was carried out by examining all laws and regulations that are related to the legal issue that is being handled. For study of academic activities, researchers need to find the ratio legis and the ontologism basis of the birth of the law. So a relevant rule can be found to solve the problem. The conceptual approach was carried out by

looking for existing theories and doctrines to be used as a reference in order to understand views and doctrines in building a legal argument in solving the issue at hand.

## Results and Discussion

The government has an obligation to provide legal protection to the community. This protection is given to the community so that they can enjoy all the rights that is provided by the law or in other words, legal protection is a variety of legal remedies that must be provided by law enforcement officials to provide a sense of security, both mindfully and physically from interference and various threats from any party.

Based on the objectives to be achieved and the policies to be implemented, the steps that can be taken by the government are: Regulation and assessment, Production supervision, Distribution supervision, Business coaching and development, and Improvement and development of infrastructure and personnel,

One of the roles of government in supporting children's health is the provision of vaccines during child immunization. In this case, vaccines in children are biological products that are consumed by children. Regulation of the Head of the Drug and Food Supervisory Agency Number 12 of 2015 concerning Supervision of the Importation of Drugs and Food into the Territory of Indonesia Article 1 number 8 states that Biological Products are vaccines, immunosera, antigens, hormones, enzymes, blood products and other fermented products (including monoclonal antibodies. and products derived from recombinant DNA technology) which are used to influence/investigate physiological system or pathological condition in the context of prevention, cure, restoration and improvement of health (Ranuh, 2008).

So far, fake vaccines are not only circulating in Java. However, fake vaccines were found to have spread to Sumatra and its surroundings. According to the information from the Food and Drug Supervisory Agency (hereinafter abbreviated as BPOM), at least the distribution is in 9 provinces, namely Pekanbaru (Riau), Palembang (South Sumatra), Bandar Lampung (Lampung), Serang (Banten), DKI Jakarta, Bandung (West Java) , Surabaya (East Java), Pangkal Pinang (Babel), and Batam. The Food and Drug Supervisory Agency (hereinafter abbreviated to as BPOM) stated that at least 12 fake vaccines had been found. This vaccine is reported to have the trademarks of PT Biofarma, PT Sanofi Group, and PT Glaxo Smith Kline. The list of fake vaccines in these children includes:

Tabel 1. List of Fake Vaccines in Children

Number	Type of Vaccines
1	Engerix B vaccine
2	Pediacel vaccine
3	Eruvax B vaccine
4	Tripacel vaccine
5	PPDRT23 vaccine
6	Penta-bio vaccine
7	TT vaccine
8	Measles vaccine
9	Hepatitis B vaccine
10	Polio bOPV vaccine
11	BCG Vaccine
12	Harvix vaccine

The government plays a role in forming regulations and law enforcement through various goods control activities. However, business actors have an equally important role to commit to consumer protection regulations. The Consumer Protection Law cannot run only by relying on the role of the government in forming regulations and law enforcement through various goods control activities (Saragih, 1895; Gunawan, 2004; Kurniawan, 2011). But this is the time for business actors as “friends” of the government to be able to participate in enforcing consumer protection.

Regulation of the Minister of Health Number 33 of 2016 concerning the Administration of Drug Quality Tests in Government Pharmacy Installations Article 1 number 3 states that laboratory test carried out to prove the quality of drugs consistently meet standards and requirements. So that before being distributed to the community, it must be tested first, the administration of drug quality testing at the Government Pharmacy Installation is carried out by BPOM through the following activities: Sampling; Laboratory test; and Reporting of test results.

In connection with the report of quality test result, guidance and supervision was carried out as regulated in Article 7 of the Minister of Health Regulation Number 33 of 2016 concerning the Administration of Drug Quality Tests in Government Pharmacy Installations carried out by the Minister, Head of BPOM, Head of Provincial Health Service, and Head of District/City Health Office according to their respective duties and functions. So every government hierarchy in Indonesia has a function of supervising drug distribution, including vaccines for children.

The efforts made by the government to prevent the distribution of vaccines to children include: There is cooperation between the government (Ministry of Health (hereinafter abbreviated as Depkes), police, court and prosecutor) and producers of child vaccines, The government must guarantee every citizen to live a healthy life by using the best standard ingredients, Supervise the distribution of child vaccines sold in the market (both at pharmacies and those already circulating in Public health center and Integrated Healthcare Center (hereinafter referred to as posyandu). And also providing correct information to the community in order to expand knowledge about vaccines with good standards.

### **Business Actors’ Liability for Consumer Losses**

Liability based on negligence is a subjective principle of responsibility, namely a responsibility determined by the producer actor. Based on this theory, producer negligence which resulted in the emergence of consumer losses to file claims for compensation against producers. Liability for the distribution of fake vaccines to children means the liability of producers of products that harm consumers because of things that can be detrimental to health, especially for children and consumers who buy these products will get losses in their health.

Furthermore, any consumer complaint against losses that is suffered by business actors can be pursued in 2 ways as referred to in article 45 paragraph (1) of the Consumer Protection Law: Lawsuits against business actors through institutions that are in charge of resolving disputes between consumers and producers outside the court, in this case BPKN, LPKSM and BPSK. And also Lawsuit against business actors through a public court uses the provisions of civil procedural law, as in the settlement of civil cases in general.

Responsibility in product liability applies the strict liability principle, the producer can free himself/herself from its responsibility, either in whole or in part. Things that can release the responsibility of these producers are: If the producer does not put the product into circulation; The defect that caused the loss did not exist when the product was distributed by the manufacturer, or the defect occurred only later; That the product is not made by the producer

either to be sold or to be distributed for economic purposes or to be made or circulated for business purposes; That the occurrence of defects in the product is due to the obligation to fulfill the obligations stipulated in the regulations that is issued by the government; That scientifically and technically (state of scientific and technical knowledge, state of defense) when the product is distributed, defects are unlikely to occur.

Based on the existing legal system, the position of consumers is very weak compared to producers. One of the efforts to protect and improve the position of consumers is by applying the principle of strict liability in the law regarding the responsibility of producers. With the implementation of the principle of strict liability, it is also hoped that Indonesian producers or industrialists will realize how important it is to maintain the quality of the products that they produce, because otherwise it will harm consumers, there will also be a very large risk to be borne. Producers will be more careful in producing before they are put on the market so that consumers, both domestic and foreign, will not hesitate to buy goods produced by Indonesia.

The obligation of business actors to always have good intentions in carrying out their business activities as stated in Article 7 of the Consumer Protection Law, means that business actors are responsible for creating a healthy business climate in order to support national development. Obviously, this is a public responsibility that business actors producer carry. For every violation that is carried out by a business actor producer, he/she will be subject to legal sanctions, both administrative and criminal sanctions. Some actions that are contrary to the aim of creating a healthy business climate can be categorized as criminal acts.

The distribution of fake vaccines to children, which has been mentioned, clearly has a negative impact on children. Vaccines that is administered to immunize children have the function of providing immunity to infants and children so that the body makes anti-substances to prevent certain diseases (Purnamasari et al, 2020; Jaya et al, 2019). However, the fact is that many people misuse vaccines by making fake vaccines resembling the real ones for profit. In this case the government plays a role in preventing and overcoming so that the distribution of fake vaccines does not happen again and consumers get their right, namely vaccines to prevent disease.

The State, Government, Local Government, Community, Family, and Parents or Guardians are obliged and responsible for the Administration of Child Protection. Article 20 of Law Number 35 of 2014 concerning Amendments to Law Number 23 of 2002 concerning Child Protection, mandates that protection of children is the responsibility of the government.

Every person who is harmed by an act/negligence incident, is not careful, has the right to get compensation for the loss. However, to obtain the right to compensation, the law imposes proof of the guilt of another person in the incident to those who sued for compensation. Liability for the distribution of fake vaccines to children means the liability of producers of health products that harm consumers because of things that can harm the health of the immune system in children.

The consumer's lawsuit against the business actor may be subject to a lawsuit against the law, because it causes losses to the products consumed by the community and the communities as consumers feel disadvantaged by the fake vaccine. In order to provide more legal protection to consumers, Indonesia enacted the Consumer Protection Law. The Consumer Protection Law also regulates the provisions for defective products, but Article 11 letter (b) of the Consumer Protection Law uses the term hidden defects and in Article 8 paragraph (2) and (3) the Consumer Protection Law uses the term defect or used.

## Conclusion

The development of consumer protection that is carried out by the government is an effort to ensure that the rights of consumers and business actors are obtained as well as their respective obligations are carried out in accordance with the principle of justice and the principle of balance of interests. The Minister of Health and BPOM, as the institution that supervise the distribution of child vaccines, must cooperate each other so that fake vaccines are not circulated by individuals or companies. And in supervising the distribution of child vaccines, cooperation with non-governmental consumer protection organizations can also be carried out, so that the community as consumers can fulfill their rights as consumers that must be fulfilled. One of the efforts to protect and improve the position of consumers is by applying the principle of strict liability in the legal regarding the responsibility of producers. Consumers can carry out civil suit based on actions against the law of Article 1365 BW and consumers also have the right to litigation suit through judicial channels based on Article 45 paragraph (2) of the Consumer Protection Law. The liability that is carried out by the consumer is a form of responsibility that must be carried out by the business actor for losses suffered by the consumer.

### Acknowledgement

Ms. Pepen, Staff from BPOM to be the source of information

### References

- Detmer, D., Bloomrosen, M., Raymond, B., & Tang, P. (2008). Integrated personal health records: transformative tools for consumer-centric care. *BMC medical informatics and decision making*, 8(1), 1-14.
- Gunawan, J. (2004). *Product Liability dalam Hukum Bisnis Indonesia* [orasi ilmiah dalam rangka Dies Natalis XXXIX]. Bandung: Unika Parahyangan Bandung.
- Jaya, L. P., Auerkari, R., & Wahyu, A. (2019). The Challenges and Opportunities of Women's Role in Child Immunization. In *2nd International Conference on Strategic and Global Studies (ICSGS 2018)*. Atlantis Press.
- Kurniawan. (2011). *Hukum Perlindungan Konsumen*. Malang Universitas Brawijaya Press.
- Purnamasari, E., Lubis, N. L., & Ashar, T. (2020). The Effect of Counseling with Lecture and Leaflet Methods on Knowledge and Attitudes of Pregnant Women in Providing Basic Immunization. *Budapest International Research and Critics Institute (BIRCI-Journal): Humanities and Social Sciences*, 3(2), 956-964.
- Ranuh, I. G. N. (2008). *Pedoman Imunisasi di Indonesia*. Eds. Ketiga. Badan Penerbit Ikatan Dokter Anak Indonesia.
- Saragih, D. (1985). *Pokok-Pokok Hukum Perikatan*, Terjemahan dari J.H. Niuwenhuis, judul asli *Hoofdstuken Verbintenissenrecht*. Surabaya Universitas Airlangga.
- Wilson, T. A. (2012). Supporting social enterprises to support vulnerable consumers: the example of community development finance institutions and financial exclusion. *Journal of consumer policy*, 35(2), 197-213.