Regulations for Organizing Immunizations in Indonesia

Regulasi Penyelenggaraan Imunisasi di Indonesia

Sabda Wahab^{1*}; Irman Idrus²; Hilda Muliana³; Nia Azzahra⁴ email : ¹sabdaboda8@gmail.com

¹ Student Of Law Study Program Doctoral Program Faculty Of Law, University 17 August 1945 Semarang

¹ Health Faculity, Anak Bangsa University ²Department of Pharmacy, Institute of Pelita Ibu Health Sciences Kendari ³ Department of Pharmacy, Batam University

Abstract: Immunization is an effort to increase a person's immunity through administration of antigens to prevent certain diseases which are packaged in the form of programs organized by the Government in the implementation of preventive health efforts. In 2021 only 79.6% of children in Indonesia will receive complete basic immunization. The purpose of this research is to find out the regulations related to the administration of immunization in Indonesia. This research is descriptive research with a normative juridical approach and the type of research is library research. Secondary data collection was carried out using library materials, namely in the form of primary, secondary and tertiary legal materials, then a qualitative analysis was carried out. Stipulation of PMK Number 12 of 2017 concerning Organizing Immunizations is in accordance with statutory provisions, because it is ordered by Law Number 36 of 2009 concerning Health. Implementation of Immunizations based on PMK Number 12 of 2017 includes types of immunization, implementation of program immunizations, implementation of selected immunizations, Monitoring and Management of AEFI, Research and Development, Community Participation, Recording and Reporting, Guidance and Supervision which aims to maintain children's health so that they are free from infectious diseases, but immunization has not run optimally, this can be seen from the IDL coverage rate which is still high, this is caused by several obstacles, one of which is the refusal of parents regarding immunization for children, this is due to the absence of strict sanctions regarding refusal of immunization.

Keywords: IDL, Implementation of Immunization, Regulation, Children

Abstrak: Imunisasi adalah upaya peningkatan kekebalan tubuh seseorang melalui pemberian antigen untuk mencegah penyakit tertentu yang dikemas dalam bentuk program yang diselenggarakan oleh Pemerintah dalam pelaksanaan upaya kesehatan preventif. Pada tahun 2021 hanya 79,6% anak di Indonesia yang mendapatkan imunisasi dasar lengkap. Tujuan dari penelitian ini adalah untuk mengetahui regulasi terkait penyelenggaraan imunisasi di Indonesia. Penelitian ini merupakan penelitian deskriptif dengan pendekatan yuridis normatif dan jenis penelitiannya adalah penelitian kepustakaan. Pengumpulan data sekunder dilakukan dengan menggunakan bahan kepustakaan yaitu berupa bahan hukum primer, sekunder dan tersier, selanjutnya dilakukan analisis kualitatif. Penetapan PMK Nomor 12 Tahun 2017 tentang Penyelenggaraan Imunisasi sudah sesuai dengan ketentuan peraturan perundangundangan, karena diperintahkan oleh Undang-Undang Nomor 36 Tahun 2009 tentang Kesehatan. Pelaksanaan Imunisasi berdasarkan PMK Nomor 12 Tahun 2017 meliputi jenis imunisasi, pelaksanaan program imunisasi, pelaksanaan imunisasi terpilih, Pemantauan dan Pengelolaan KIPI, Penelitian dan Pengembangan, Partisipasi Masyarakat, Pencatatan dan Pelaporan, Pembinaan dan Pengawasan yang bertujuan untuk menjaga kesehatan agar bebas dari penyakit menular, namun imunisasi belum berjalan maksimal, hal ini terlihat dari angka cakupan IDL yang masih tinggi, hal ini disebabkan oleh beberapa kendala salah satunya adalah penolakan orang tua mengenai imunisasi pada anak, hal ini disebabkan belum adanya sanksi yang tegas terkait penolakan imunisasi.

Kata Kunci: IDL, Pelaksanaan Imunisasi, Regulasi, Anak

INTRODUCTION

Health has an important role in development and is one of the elements of general welfare that must be realized following the ideals of the Indonesian nation as referred to in the 1945 Constitution (Wahab, 2020). It is the government's responsibility to maintain the health of all citizens and avoid various diseases, especially infectious diseases, through integrated health programs supported by valid epidemiological data and information. Various efforts have been made by the government to combat the endemic spread of various infectious diseases, one of which is with an early immunization program. The immunization program is the duty and responsibility of the Ministry of Health which has to carry out immunization programs for people in all regions of Indonesia (Nuryanah, 2020).

In 2018 WHO said there were still around 20 million children in the world who had not received immunizations (Keminfo, 2019), Indonesia is one of the countries with a large number of children who do not get complete immunization. This situation has resulted in the emergence of Extraordinary Events (KLB) of immunization-preventable diseases (PD3I) such as diphtheria, measles, and polio. Immunization is very important for the growth and development of children because it protects against various diseases and disabilities. The National Immunization Program is part of the Ministry of Health's plan to prevent disease, disability and death from diseases that can be prevented through immunization in children and adults. The Indonesian Immunization Program is a government program implemented within the framework of public health policy. The term national immunization program is a variant of the Immunology Development Program which was initially focused on preventing diseases that could be prevented by immunization in children. Every country has a national immunization program to protect people from vaccine-preventable diseases.

The government through the Ministry of Health noted that since 2018, only 87.8% of children have received complete basic immunization (Kemenkes RI, 2019), even in 2020 the coverage of complete basic immunization in infants will drop drastically where the immunization coverage achieved is only 84%. Leaving children who have not been exposed to the immunization program organized by the Ministry of Health, there are more than 1.7 million babies who have not received basic immunizations during the 2019-2021 period (Kemenkes RI, 2022). In 2021, during the Covid-19 pandemic that hit Indonesia, immunization coverage dropped dramatically to 79.6 percent (Dina Manafe, 2013). Individual and group immunization programs are now mandated to be able to maintain the health of the local community (Sudjadi *et al.*, 2017). Based on the implementation, there are several types of immunization, namely routine immunization and follow-up immunization (Hadianti *et al.*, 2014).

The government implements the immunization program through the Ministry of Health and its agencies as well as coordination between related agencies. The implementation of community immunization is very important because vaccines protect the health of a person or the health of individuals, because unlike other health initiatives, vaccines maintain the health of healthy people, remove major obstacles to child development, and vaccines can protect every individual and community who are immunized. Implementation of individual and group immunization programs is currently required to maintain public health. In practice, there are two types of immunization, namely routine immunization and follow-up immunization.

Immunization is the right of every child because immunization can protect every child from infectious disease infections that can cause serious complications, disability, or even death in children. By immunizing children, they have immunity against diseases such as polio, measles, rubella, hepatitis B, and others. Immunization is a right that must be given without having to be asked by the child, because the right to health is a natural right given by God Almighty since the child was born, so that everyone is obliged to protect the child's rights. This is in line with the provisions of the Convention on the Rights of the Child adopted by the Government of Indonesia

through Presidential Decree Number 36 of 1990 concerning Ratification of the Convention on the Rights of the Child (Convention on the Rights of the Child) which regulates in general the principles of child protection (Saraswati R, 2015). There are several laws that regulate the rights and protection of children in Indonesia, including Law Number 39 of 1999 concerning Human Rights, Law Number 23 of 2002 concerning Child Protection Juncto Law Number 35 of 2014 concerning amendments to the Law -Law Number 23 of 2002 concerning Child Protection Juncto Law of the Republic of Indonesia Number 17 of 2016 concerning the Stipulation of Government Regulations in Lieu of Law Number 1 of 2016 concerning the Second Amendment to Law Number 23 of 2002 concerning Child Protection Becomes Law

Law Number 35 of 2014 concerning Child Protection states that children's rights are rights that must be guaranteed, protected, and fulfilled by all relevant parties, namely parents, family, community, state, government, and local government. Then in Article 1 paragraph 13, it is also stated that special protection is a form of protection received by children in certain situations and conditions to get a guarantee of a sense of security against threats that endanger themselves and their lives in their development.

Based on these regulations it can be concluded that children have the right to guarantee a sense of security both physically and mentally, including in the health sector. There is no party in this world today that is not in contact with the issue of child protection, including in the health sector. Therefore, efforts are needed by the government to improve the health status of children.

Optimal child health status can be achieved through several health efforts including preventive, curative, promotive, and rehabilitative efforts so that plenary health efforts are established. As is well known, curative efforts are very important, but no less important are preventive efforts. Preventive efforts are now efforts that are being encouraged by the DPRRI and the Government to establish Law Number 36 of 2009 concerning Health, one of which regulates the eradication and control of infectious diseases and regulates preventive health efforts through immunization.

Realization of Law Number 36 of 2009 concerning Health concerning preventive efforts through immunization, implementing regulations have been formed in the form of a Minister of Health Regulation, namely Regulation of the Minister of Health Number 12 of 2017 concerning Implementation of Immunizations, it is explained that immunization is an effort to prevent disease given to someone through attenuated viruses or bacteria. Immunization is given to protect a child and the community so that they can avoid various diseases, especially diseases that can be prevented by immunization. Therefore, immunization must be given to children from the time the child is born up to the age of 9 months (Hadianti *et al.*, 2014).

The implementation of immunization in Indonesia based on PMK Number 12 of 2017 has not run optimally, it can be seen from several obstacles, the first is environmental conditions that do not support the implementation of the immunization program where there is still a lack of parental support for toddlers in obtaining immunizations so that immunization coverage in Indonesia is still low . Secondly, Extraordinary Events (KLB) still occur after the immunization program is running. Based on research by Yunilia, Putera and Lufsiana (2021) states that a factor that can influence the occurrence of an outbreak is an error in vaccine storage, so that the vaccine used cannot work effectively. Second, there is the spread of fake vaccines given by health workers in health facilities. The spread of counterfeit vaccines should not have occurred, because there is a vaccine distribution permit regulation that has been stipulated by the Government in PMK Number 12 of 2017 concerning Implementation of Immunizations in Article 3 paragraph 1 states that, Vaccines for Program Immunizations and Selected Immunizations must have a distribution permit in accordance with regulatory provisions legislation. This means that the vaccine being distributed must have been approved and registered by the authorities so that it can be distributed in the territory of Indonesia. The three factors of communication and coordination between the implementers of the immunization program have not gone well, namely the lack of communication and coordination between the Surveillance and Immunization Section at the Health Office and health cadres at the village level in implementing the immunization program, and the four resources that are owned are still lacking, as where there is still a lack of access to remote areas or villages which makes it difficult for officers to carry out their duties optimally, so that the immunization program is not running optimally.

RESEARCH METHODS

The type of research in writing this paper is normative juridical, which means the approach is carried out by examining the approaches of theories, and concepts, and studying the laws and regulations concerned with this research or the statutory approach (Irwansyah, 2020). Normative juridical research is legal research that places law as a building system of norms. The norm system in question is regarding principles, norms, rules of law, agreements, and doctrines (teachings). This normative research is research on legal systematics, namely research whose main objective is to identify the notions or basis in law (Sunggono, 2016). This type of research was used because the researcher wanted to examine everything related to the regulations for administering immunization in Indonesia. The specifications used in this study are analytical descriptive, which describes the applicable laws and regulations with legal theories and the practice of implementing positive law concerning the problems that have been formulated (Soekanto, 2010). Research data is secondary data by collecting data through literature. Data analysis uses qualitative analysis which is used to discuss regulations for administering immunization in Indonesia (Ikhsan and Wahab, 2021).

DISCUSSION

A. Legal Basis for Immunization in Indonesia

In forming laws and regulations, there are several theories that need to be understood by designers, namely the theory of levels of norms. Hans Nawiasky, one of Hans Kelsen's students, developed his teacher's theory of the theory of levels of norms in relation to a country. Hans Nawiasky in his book "Allgemeine Rechtslehre" argues that according to Hans Kelsen's theory, a state legal norm is always layered and tiered, that is, the norm below applies, is based on, and originates from a higher norm and so on up to a norm that The highest is called the basic norm. From this theory, Hans Nawiasky added that apart from the fact that norms are layered and tiered, legal norms also come in groups. Nawiasky groups them into 4 major groups namely: Staatsfundamentalnorm; Staatsgrundgezets; Formell Gezetz; Verordnung and Autonome Satzung (Berry, 2018).

The legal force of statutory regulations is in accordance with their hierarchy, in which the 1945 Constitution is the highest regulation in the Indonesian legal system and forms the basis for the statutory regulations below it (Irawan, Wibowo and Minollah, 2023). Legislation theory is a written regulation that contains generally binding legal norms formed or formed by state institutions or officials, who have authority through the procedures stipulated in statutory regulations. The lower hierarchy of laws and regulations may not conflict with higher laws and regulations (Fitryantica, 2019).

The Indonesian nation as referred to in Pancasila and the 1945 Constitution of the Republic of Indonesia has the aspiration to guarantee the health and welfare of the people. This health can be realized if the community gets quality health services. Health services include individual health services and community health services through preventive or preventive, curative or treatment, and rehabilitative or recovery efforts. To improve public health status and maintain the health status of all Indonesian people, immunization is needed as a preventive action.

Immunization is a primary prevention effort to avoid illness or events that can cause someone to

get sick or suffer from injury and disability. Immunization is a long-term program, which has been designed for more or less 20 years. This is based on the legal basis of the 1945 Constitution.

Article 28 B paragraph (2) states:

"Every child has the right to survival, growth, and development, and is entitled to protection from violent discrimination"

Article 28 H paragraph (1) states:

"Every person has the right to physical and spiritual well-being, a place to live and a good and healthy living environment, and the right to obtain health services."

The government must guarantee complete immunization for every baby and child according to the needs and rights of the child. The provision of immunization is to prevent and protect children from diseases that can be prevented by immunization and of course, must be following applicable regulations.

Law Number 35 of 2014 concerning Child Protection, Article 1 states that:

"Child Protection is all activities to guarantee and protect children and their rights so that they can live, grow, develop and participate optimally following human dignity and values, and receive protection from violence and discrimination."

This statement is in line with Law Number 36 of 2009 concerning Health, Article 130 states that:

"The government is obliged to provide complete immunization to every baby and child."

Article 132 states that:

- (1) The child who is born must be raised and cared for responsibly to enable the child to grow and develop healthily and optimally.
- (2) Provisions regarding children born as referred to in paragraph (1) are carried out following statutory regulations.
- (3) Every child has the right to receive basic immunization following applicable provisions to prevent the occurrence of diseases that can be avoided through immunization."

Article 153:

"The government guarantees the availability of safe, quality, effective, affordable, and equitable immunization materials for the community for efforts to control infectious diseases through immunization."

Based on the provisions above, it can be concluded that every Indonesian child has the right to receive complete immunization to prevent certain diseases. The vaccines given are provided by the government so that immunization can be of maximum efficiency because the government must ensure the availability of immunization materials that are safe, of good quality, effective, affordable, and equitable.

B. Regulations for Organizing Immunizations in Indonesia

In the hierarchy of laws and regulations, Regulations of the Minister of Health are included in the category of laws and regulations stipulated by the Minister of Health in the context of carrying out his duties and authorities. Based on Article 8 paragraph (2) of Law Number 12 of 2011 concerning Formation of Legislation, it is explained that Regulations of the Minister of Health are recognized and have binding legal force as long as they are ordered by higher Legislation or formed based on authority.

PMK Number 12 of 2017 concerning Implementation of immunization is determined based on the provisions of Article 132 paragraph (4) of Law Number 36 of 2009 concerning Health. Or we can look at the juridical basis of PMK Number 12 of 2017. The juridical basis is a consideration or reason that illustrates that regulations are formed to resolve legal issues or fill legal voids by taking into account existing regulations, which will be changed, or which will be repealed to guarantee

certainty. law and a sense of social justice. The juridical element concerns legal issues relating to the substance or material being regulated so that it is necessary to form new laws and regulations. So that the stipulation of PMK Number 12 of 2017 is in accordance with the mandate of Law Number 36 of 2009 concerning Health.

PMK Number 12 of 2017 has several main functions, including:

- 1. Creating consistent standards for administering immunization: PMK Number 12 of 2017 harmonizes and provides clear standard guidelines for administering immunization in all regions of Indonesia. This helps create consistency in the immunization process and ensures that the immunization services provided meet established quality standards.
- 2. Ensuring immunization safety and security: This regulation provides guidelines regarding procedures for storing, transporting and handling vaccines and equipment used in administering immunizations. The goal is to ensure the safety and security of the vaccine given to the individual to be vaccinated.
- 3. Regulate medical records and immunization reporting: PMK Number 12 of 2017 stipulates requirements regarding immunization recording and reporting. This is important for monitoring immunization coverage, identifying unvaccinated individuals, and ensuring accurate reporting of immunizations at the national level.
- 4. Regulates the obligations of immunization agents: This regulation provides provisions regarding the obligations of immunization agents, including health workers who give vaccinations and parties involved in administering immunizations, such as health institutions, health centers, and hospitals. The aim is to ensure that there is responsibility and accountability in administering immunization.
- 5. Provide guidelines regarding vaccination of special groups: Permenkes Number 12 of 2017 also regulates vaccination of special groups, such as premature babies, babies with low birth weight, children with immune deficiencies or chronic diseases, pregnant women, and certain risk populations. It is important to ensure that these groups receive the immunization protection they need.

Implementation of immunization in Indonesia is regulated by Regulation of the Minister of Health Number 12 of 2017 concerning Implementation of Immunizations. The scope of these regulations includes:

- 1. Type of Immunization
- 2. Organizing the Immunization Program
- 3. Implementation of Selected Immunizations
- 4. Monitoring and control of AEFI (Post-Immunization Follow-up Events)
- 5. Research and development
- 6. Community participation
- 7. Recording and reporting
- 8. guidance and supervision.

Based on the type of implementation, immunizations are grouped into Program Immunizations and Selected Immunizations. Article 1 Point 3 of Regulation of the Minister of Health Number 12 of 2017 concerning the Implementation of Immunizations explains that: "Program Immunizations are immunizations that are mandatory for a person as part of the community to protect the person concerned and the surrounding community from diseases that can be prevented by immunization."

The Minister may determine the type of Immunization Program other than those regulated in this Ministerial Regulation by considering the recommendation of the National Immunization Expert Advisory Committee (Indonesian Technical Advisory Group on Immunization). The introduction of new immunizations into immunization programs can be preceded by a campaign or demonstration of the program at selected locations according to the epidemiology of the disease.

In addition, in the Appendix it is also explained that immunization is given to healthy targets and that before administering immunization, screening is needed to assess the condition of the target. Target screening procedures include:

- 1. Target condition;
- 2. Types and benefits of vaccines given;
- 3. Consequences if not immunized;
- 4. Possible AEFIs and measures to be taken; and
- 5. Next Immunization Schedule.
- 6. Program Immunization based on PERMENKES Number 12 of 2017.

Article 4 paragraph, states that:

- (1) Program immunization consists of:
 - a. Routine immunization;
 - b. Additional immunization; and
 - c. Special immunization.
- (2) Program immunizations must be given according to the type of vaccine, schedule, or time of administration specified in the Immunization Organizing Guidelines as listed in the Appendix which is an integral part of this Ministerial Regulation.

Based on the article above, it can be seen that there are 3 immunization programs, namely routine immunization, additional immunization, and special immunization, namely with different types of immunization and different times of administration.

Article 5 states that:

- (1) Routine immunization is carried out continuously and continuously.
- (2) Routine immunization consists of basic immunization and advanced immunization.

Article 6 states that:

- (1) Basic immunization referred to in Article 5 paragraph (2) is given to babies before they are 1 (one) year old.
- (2) Basic immunization as referred to in paragraph (1) consists of immunization against diseases:
 - 1. Hepatitis B;
 - 2. Poliomyelitis;
 - 3. tuberculosis;
 - 4. Diphtheria;
 - 5. pertussis;
 - 6. Tetanus;
 - 7. Pneumonia and meningitis caused by Hemophilus Influenza type b (Hib); and
 - 8. Measles.

Article 7 states that:

- (1) Follow-up immunization as referred to in Article 5 paragraph (2) is a repeat basic immunization to maintain the level of immunity and to extend the protection period for children who have received basic immunization.
- (2) Advanced immunization as referred to in paragraph (1) is given to:
 - a. children under two years old (Baduta);
 - b. elementary school-age children; and
 - c. women of childbearing age (WUS).
- (3) Further immunization given to Baduta as referred to in paragraph (2) letter a consists of immunization against diphtheria, pertussis, tetanus, hepatitis B, pneumonia, and meningitis caused by Hemophilus Influenza type b (Hib), and measles.
- (4) Advanced immunization is given to children of primary school age as referred to in paragraph (2) letter b consists of immunization against measles, tetanus, and diphtheria.

- (5) Advanced immunization given to children of primary school age as referred to in paragraph (4) is given in the month of school child immunization (BIAS) which is integrated with school health efforts.
- (6) Advanced immunization given to WUS as referred to in paragraph (2) letter c consists of immunization against tetanus and diphtheria.

So based on Articles 5, 6, and 7 it can be concluded that routine immunization consists of basic immunization and advanced immunization. Basic immunizations must be given to babies from birth to 9 months of age. Basic immunization in the form of protection against Hepatitis B, Poliomyelitis, tuberculosis, diphtheria, pertussis, tetanus, pneumonia, and meningitis caused by Hemophilus influenza type B (HIB), measles, and rubella. Follow-up immunization is a repeat of basic immunization to maintain the level of immunity and to extend the protection period for children who have received basic immunization. Advanced immunization is given to children under two years old (Padua), school-age children, and women of childbearing age. Advanced immunization for children under two is given at the age of 18 months in the form of DPT-Hep B-HIB and measles immunizations. Meanwhile, school-age children receive additional immunizations during the school children's immunization month (BIAS) in the form of measles and DT immunizations (class I), Td (class II), and Td (grade 5).

Article 8 states that:

- (1) Additional immunization is a certain type of immunization that is given to certain age groups who are most at risk of disease according to epidemiological studies at a certain period. (2)
- (2) Provision of additional immunizations as referred to in paragraph (1) is carried out to complete basic and/or advanced immunization on targets that have not been achieved.
- (3) The provision of additional immunizations as referred to in paragraph (1) does not eliminate the obligation to provide routine immunizations.
- (4) Determination of the provision of additional immunization based on the epidemiological study as referred to in paragraph (1) is carried out by the Minister, head of the provincial health office, or head of the district/city health office.

Based on the article above, it can be explained that additional immunization is an immunization program that is carried out to achieve certain targets to achieve certain coverage rates. Or immunization programs implemented by the government to prevent the occurrence of a particular disease. One form of additional immunization is National Immunization Week (PIN), which is a mass immunization activity carried out simultaneously in a country in a short time. PIN aims to break the chain of the spread of disease and increase herd immunity (eg polio, measles, or other immunizations). Immunizations given to PINs are given regardless of previous immunization status.

Article 9 states that:

- (1) Specific immunizations are carried out to protect individuals and communities against certain diseases in certain situations.
- (2) Certain situations as referred to in paragraph (1) are in the form of preparations for the departure of prospective Hajj/Umroh pilgrims, preparations for travel to or from endemic countries of certain diseases, and conditions of extraordinary events/outbreaks of certain diseases.
- (3) Special immunizations as referred to in paragraph (1) are in the form of immunizations against meningococcal meningitis, yellow fever, rabies, and poliomyelitis.
- (4) The Minister can determine certain situations on special immunizations other than the situations referred to in paragraph (2).

Based on the article above, it can be explained that special immunizations are carried out to protect individuals and communities against certain diseases and certain situations, for example, preparation for prospective Hajj/Umrah pilgrims, preparation for travel to or from certain disease-

endemic areas, and certain disease outbreak conditions. This special immunization can be in the form of immunization against meningococcal meningitis, yellow fever (yellow fever), rabies, and poliomyelitis.

Article 25 states that:

- (1) Program Immunization Services can be carried out in bulk or individually.
- (2) Program Immunization Services as referred to in paragraph (1) are carried out using a family approach to increase access to immunization services
- (3) Mass Program Immunization Services as referred to in paragraph (1) are carried out at Posyandu, schools, or other immunization service posts.
- (4) (1) Individual program immunization services as referred to in paragraph (1) are carried out in hospitals, health centers, clinics, and other healthcare facilities.

Immunization program services can be provided in bulk or individually. Mass services can be provided at Posyandu, schools, and other places. Then individual services can be obtained at hospitals, health centers, clinics, and other healthcare facilities.

Article 26 states that:

- (1) Every health service facility that provides program immunization services is required to use vaccines provided by the central government.
- (2) Excluded from the provisions referred to in paragraph (1):
 - a. based on medical reasons that do not allow the vaccine provided by the Central Government as evidenced by a doctor's certificate or valid medical document; or
 - b. if the parent/guardian of the child refuses to use the vaccine provided by the Central Government.
- (3) Health service facilities that violate the provisions referred to in paragraph (1) are subject to administrative sanctions in the form of:
 - a. written warning; and/or
 - b. license revocation.
- (4) The sanctions referred to in paragraph (3) are given by the Minister or Regional Government following their respective authorities.

The article above clearly states that the vaccines injected into children are vaccines provided by the government unless there is a doctor's statement that does not recommend the child to get the vaccine from the government and the parents do not agree to be given a vaccine from the government. Vaccines for Program Immunizations and Selected Immunizations must have distribution permits following statutory provisions.

Article 27 states that:

- (1) The implementation of routine immunization services must be planned by health service facilities providing regular and continuous immunization services.
- (2) The planning as referred to in paragraph (1) includes the schedule for implementation, the place for implementation, and the implementation of Immunization services.

Routine immunization services will usually be carried out on a scheduled basis either at the Puskesmas or at the health clinic. Health facilities will schedule every day for immunization services to be carried out because the vaccines used cannot last long so scheduling vaccine use is more effective and no vaccine is wasted.

Article 28 states that:

- (1) District/City local governments are responsible for preparing operational costs for the implementation of routine immunization services and additional immunization at health centers, posyandu, schools, and other immunization service posts.
- (2) Operational costs as referred to in paragraph (1) include costs:
 - a. Transport and accommodation for officers;
 - b. consumables;
 - c. community mobilization;

- d. Repair and maintenance of Cold Chain equipment and Immunization vehicles;
- e. Logistics distribution from district/city areas to health service facilities; and
- f. Destruction of medical waste Immunization.

Based on the article above, it is explained that the operational costs of administering immunization are borne by the local government. However, if immunization is carried out in a private clinic, there will be a fee billed to the community for immunization services.

Article 30 states that;

Program Immunization Services are carried out by health workers who have the competence and authority to follow statutory provisions.

Article 31 states that:

The process of administering immunization must pay attention:

- a. Safety, quality, and efficacy of vaccines used; and
- b. Safe injection (safety injection) to prevent transmission of disease to health workers who carry out immunization services and the community and to prevent AEFI.

So Articles 30 and 31 of the Regulation of the Minister of Health of the Republic of Indonesia Number 12 of 2017 concerning the Implementation of Immunizations found that immunizations can be given by competent health workers with due regard to infection prevention, vaccine expiration dates to prevent post-immunization events.

Article 32 states that:

- (1) Before program immunization services, health workers must provide an explanation of immunization including the type of vaccine to be given, benefits, consequences if not immunized, the possibility of AEFI and efforts to be made, as well as the next immunization schedule.
- (2) The explanation as referred to in paragraph (1) may use assistive devices such as mass communication media.
- (3) The arrival of the community at the Immunization service site both inside and outside the building after being explained as referred to in paragraph (1) and paragraph (2) constitutes approval for immunization.
- (4) In program immunization services, health workers must screen for contraindications to immunization targets.

Providing immunization, the client must obtain informed consent and informed choice, so that the client can understand about the immunization given. Health workers must explain the injection procedure and the side effects of giving the vaccine using communication media, for example, flipcharts or other media

Article 33 states that:

A person or group of people who take action to obstruct the implementation of Program Immunization may be subject to sanctions following the provisions of laws and regulations.

Based on the article above, it is known that sanctions will be imposed on a person or group of people who obstruct the implementation of the Immunization Program, whether intentionally or unintentionally causing someone to fail to receive immunizations, including refusing without medical reasons, may be subject to sanctions following statutory provisions.

So it can be concluded that in the Regulation of the Minister of Health of the Republic of Indonesia Number 12 of 2017 concerning the Implementation of Immunizations, program immunizations are required for every individual to protect against diseases that are prevented by the immunization program. Immunizations are given to healthy people so screening must be carried out taking into account the conditions of the targets, information about the types and benefits of vaccines and the consequences if they are not given immunizations, the possibility of AEFI, and the next immunization schedule.

Program immunizations include routine immunizations and follow-up immunizations. Routine immunization is an immunization that is carried out continuously and continuously, usually from birth to 9 months of age and is commonly called basic immunization and must be given to infants. Then for follow-up immunizations, it can be given to children under two years old (Baduta), elementary school-aged children; and women of childbearing age (WUS).

Routine immunization services will usually be carried out on a scheduled basis either at the Puskesmas or at the health clinic by obtaining services from health workers who have the competence and authority to follow statutory provisions. The immunization program should not be hindered by anyone, if this happens, sanctions will be imposed following the provisions of the law.

Article 46 states that:

- (1) The Minister, Provincial Governments, and Regency/City Regional Governments carry out guidance and supervision of the implementation of immunizations carried out by all health service facilities on a regular, tiered, and continuous basis.
- (2) In terms of supervision of Vaccines for Immunization, apart from being carried out by the Minister, Provincial Governments, and Regency/City Regional Governments, it is also carried out by heads of agencies who have duties and responsibilities in the field of drug and food control.
- (3) Guidance and supervision as referred to in paragraph (1) are directed at increasing the scope and quality of immunization services.

The guidance and supervision referred to above are one of the efforts made by the Minister, Provincial Government, and Regency/City Regional Government, BPOM on an ongoing basis for all health service facilities that carry out immunization services, especially for the vaccines provided. The supervision carried out aims to increase the coverage and quality of immunization services.

CONCLUSION

Implementation of immunization in realizing children's health rights in obtaining immunization. Stipulation of PMK Number 12 of 2017 concerning Implementation of Immunizations is in accordance with statutory provisions where this regulation was stipulated because it was ordered by a higher regulation, namely Law Number 36 of 2009 concerning health so that this regulation can become a legal basis for implementing immunization programs. Implementation of Immunizations based on PMK Number 12 of 2017 includes types of immunization, implementation of program immunizations, implementation of selected immunizations, Monitoring and Management of AEFI, Research and Development, Community Participation, Recording and Reporting, Guidance and Supervision which aims to maintain children's health so that they are free from infectious diseases, but immunization has not run optimally, this can be seen from the IDL coverage rate which is still high, this is caused by several obstacles, one of which is the refusal of parents regarding immunization for children, this is due to the absence of strict sanctions regarding refusal of immunization.

REFERENCES

Berry, M. F. (2018) 'Pembentukan Teori Peraturan Perundang-Undangan', Muhammadiyah Law Review 2, 2(2), pp. 87–91.

Dina Manafe (2013) 3,9 Juta Balita Indonesia Belum Diimunisasi, Beritasatu.com.

Fitryantica, A. (2019) 'Harmonisasi Peraturan Perundang-Undangan Indonesia melalui Konsep Omnibus Law Jurnal Gema Keadilan Jurnal Gema Keadilan', *Jurnal Gema Keadilan*, 6(3), pp. 300–316. Available at: https://ejournal2.undip.ac.id/index.php/gk/article/view/6751.

- Hadianti, D. N. et al. (2014) Buku Ajar Imunisasi, Kementerian Kesehatan RI. Jakarta: Pusat Pendidikan dan Pelatihan Tenaga Kesehatan.
- Ikhsan, M. and Wahab, S. (2021) 'Kepastian Hukum Tenaga Kefarmasian Dalam Menyelenggarakan Pelayanan Kefarmasian', *Jurnal Hukum Kesehatan Indonesia*. Masyarakat Hukum Kesehtan Indonesia (MHKI), 1(02), pp. 106–120. doi: 10.53337/JHKI.V1l02.12.
- Irawan, S., Wibowo, G. D. H. and Minollah (2023) 'Eksistensi Peraturan Daerah Kota Mataram Nomor 10 Tahun 2015 tentang Pedagang Kaki Lima dalam Meningkatkan Potensi Pajak dan Retribusi Daerah', *Mimbar Keadilan*, 16(1), pp. 115–129. Available at: https://jurnal.untag-sby.ac.id/index.php/mimbarkeadilan/article/view/8018.
- Irwansyah (2020) Penelitian Hukum : Pilihan metode dan Praktik Penulisan Artikel. Yogyakarta: Mirra Buana Media.
- Kemenkes RI (2019) *Profil Kesehatan Indonesia 2018, Health Statistics*. Edited by R. Kurniawan et al. Jakarta: Kementerian Kesehatan Repulik Indonesia. Available at: https://www.kemkes.go.id/downloads/resources/download/pusdatin/profil-kesehatan-indonesia/profil-akesehatan-indonesia-20 18.pdf.
- Kemenkes RI (2022) 2 Tahun Cakupan Imunisasi Rendah, Pemerintah Gelar Bulan Imunisasi Anak Nasional, Kementerian Keseharan Republik Indonesia.
- Kementerian Komunikasi dan Informatika (2019) PID 2019, Tingkatkan Cakupan dan Mutu Imunisasi Lengkap, Kementerian Komunikasi dan Informatika.
- Nuryanah, I. (2020) 'Implementasi Kebijakan Penyelenggaraan Imunisasi Di Kabupaten Tasikmalaya', Jurnal Administrasi dan Kebijakan Publik, 1(3), pp. 1–9.
- Peraturan Menteri Kesehatan Republik Indonesia Nomor 12 Tahun 2017 Tentang Penyelenggaraan Imunisasi (Berita Negara Republik Indonesia Tahun 2017 Nomor 559)
- Saraswati R (2015) Hukum Perlindungan Anak di Indonesia. Bandung: PT. Citra Aditya Bakti.
- Soekanto, S. (2010) Pengantar Penelitian Hukum. Jakarta: UI Press.
- Sudjadi, A. et al. (2017) 'Penerapan Pelayanan Kesehatan Masyarakat Miskin Yang Ideal Dalam Pelayanan Kesehatan Masyarakat Miskin Melalui Program Jamkesmas', SOEPRA. Soegijapranata Catholic University, 3(1), pp. 14–25. doi: 10.24167/SHK.V3I1.694.
- Sunggono, B. (2016) Metodologi Penelitian Hukum. Jakarta: Raja Grafindo Persada.
- Undang-Undang Dasar Negara Republik Indonesia Tahun 1945
- Undang-Undang Republik Indonesia Nomor 12 Tahun 2011 Tentang Pembentukan Peraturan Perundang-Undangan (Lembaran Negara Republik Indonesia Tahun 2011 Nomor 82 dan Tambahan Lembaran Negara Republik Indonesia Nomor 5234)
- Undang-Undang Republik Indonesia Nomor 36 Tahun 2009 Tentang Kesehatan (Lembaran Negara Republik Indonesia Tahun 2009 Nomor 14414 dan Tambahan Lembaran Negara Republik Indonesia Nomor 506350)
- Wahab, S. (2020) Perlindungan Hukum Terhadap Tenaga Teknis Kefarmasian Dalam Melakukan Pelayanan Kefarmasian (Studi Kasus Di Kota Ambon). Soegijapranata Catholic University. http://repository.unika.ac.id/23183/
- Yunilia, S., Putera, A. P. and Lufsiana (2021) 'Tanggung Jawab Hukum Bidan Praktik Mandiri Terhadap Penyimpanan Vaksin Imunisasi Anak', *DELEGALATA: Jurnal Ilmu Hukum*, 6(1), pp. 235–251. doi: https://doi.org/10.30596/delegalata.v6i1.5013.