UNTAG Law Review (ULREV)
Volume 1, Issue 1, May 2017, PP 37-46
ISSN 2549-4910 (online) & ISSN 2579-5279 (print)
http://jurnal.untagsmg.ac.id/indeks.php/ulrev/indeks
www.fakhukum.untagsmg.ac.id

THE MEDICOLEGAL ASPECT OF CRIMINAL VACCINES AND THEIR CONSEQUENTIAL DAMAGES

Yovita Arie Mangesti

Faculty of Law, Surakarta University

ABSTRACT : Healthy human resources will make it easier for the country to achieve development goals in the field of health The development of health sector in Indonesia currently has double burden, namely the burden of infectious diseases and degenerative diseases. For the prevention of infectious diseases, an immunization program is held in Hospitals, clinics, and physician practices. Programs that are good enough to improve public health status are tainted with the circulation of fake vaccines that are not only a medical problem, but also bring implications to the social and legal fields.

The existing regulation has not explicitly set forth the forgery of the vaccine, so in law enforcement it is still based on the interpretation of law enforcers both in determining the material law and the formal law of this medicolegal case. It is worth reviewing the role of the law as a means of social control and social engineering.

Through a conceptual approach, legislation and hermeneutics, and based on the humanitarian paradigm, this paper seeks to explore the medicolegal aspect of a fake vaccine holistically, so that law as a public guide in health can provide protection for all stakeholders involved mainly in the production, distribution and Use of the vaccine in medical care.

Case studies of fake medicolegal vaccine found that during this time, the handling of fake vaccines has not been specifically regulated and still equated with counterfeit medicines, whereas in terms of substance, the vaccine is different from the drugs.

Expectations for the creation of responsive legal protection in the field of medical services in the future, strived by reconstruction of the Health Act, a one-door management system, effectiveness and efficiency of government performance, revitalization of professional association functions and law in terms of socialization, health promotion, education, and advocacy.

Keywords : *Medicolegal, Criminal Vaccines, legal protection*

INTRODUCTION

Prevention of infectious diseases is done by immunization. Immunization in Indonesia has been held since 1956, 1997 expanded into immunization procurement program. The spread of infectious diseases is difficult because the spread does not recognize administrative boundaries. The phenomenon of the circulation of fake vaccines, is now a crucial issue in the

field of health Which has implications for legal issues. In one mass media it was reported that vaccines that did not fit the requirements sporadically have been in circulation since 2008[1]. Although some doctors believe the vaccine has no harmful effects, and the vaccination recipients are facilitated to re-vaccinate, But this has resulted in psychological losses, namely; Anxiety, traumatic experiences, the emergence of prejudices and bad image for ministers and health institutions. In addition, there is an economic disadvantage because after all the patient has purchased the vaccine and paid for medical services, it still needs extra expenses to come to the health service center to repeat the vaccination.

The law in the function of public guidance, at the applicative level is concretized in the form of current regulation. Regulation related to the use of vaccine, found in Law Number 36 Year 2009 on Health, Minister of Health Regulation No. 42 of 2013 on Immunization Implementation. But in the case of alleged circulation of fake vaccines, also enacted the provisions of Law No. 8 of 1999 on Consumer Protection, and articles in the Criminal Code[2]. If moving from the view of the positivistic paradigm where the law is a law, that without a rule in the law then an act is not included in the criminal category, the logical consequence is the article imposed outside the health legislation and the minister's regulation on immunization certainly can not Enforced because it does not mention explicitly about the vaccine. Dynamic changes certainly do not have to wait for a law that explicitly mentions about the deed, and then the perpetrators of crimes can be asked for criminal responsibility.

The above illustration raises the legal issue as the focus of this paper's review, whether current regulation is appropriate to address cases of fake medicolegal vaccines. Furthermore, with the legal consequences, how should the law be responsive to protect the interests of people in various dimensions of life.

This paper is a normative (doctrinal) study of the positive law that applies in its function as a social control instrument, using conceptual approach approach, statute approach, and hermeneutica approach to the existing regulation related to vaccine. Legal material is health laws and regulations , Hospitals, medical practice, pharmacy, Criminal Code, and other rules which overall become the basis of jurisdiction of medical services both in Indonesia.

Through this paper, it is expected that all stakeholders of medical and community services will be more aware that in the context of health services, the law serves as an instrument to protect every effort to improve health, with the finalization of the achievement of humanity and justice.

1 The sanctions given did not bring a deterrent effect, because the following year BPOM only imposed administrative sanctions on pharmaceutical wholesalers (PBF) who were caught selling fake vaccines. The latest case in the circulation of this fake vaccine is that BPOM and Bareskrim Police Headquarters received a report from PT Sanofi-Aventis Indonesia related to Sanofi vaccine products are forged in 2016. Meanwhile, the Police has set 16 suspects. At least 15 suspects have been arrested and 18 witnesses have been questioned in this case. Raids of fake vaccines were known to have penetrated five locations, namely Subang, Jakarta, South Tangerang, Bekasi, and Semarang.http://news.metrotvnews.com/hukum/gNQY4dWN-peredaran-vaksin-palsu-dalam-catatan-bpom, diakses 14 Agustus 2016, jam 07.20

2 Compare: 18 suspected cases of 2016 fake vaccines imposed money laundering, and Child Protection Article, https://m.tempo.co/read/news/106/07/12/063787082/18-tersangka-vaksin-palsu-bakal-dikenai-pasal-pencucian-uang, Accessed August 14, 2016, at 07.30, https://news.okezone.com/amp/2016/06/29/337/1428593/tersangka-vaksin-palsu-dapat-dikenakan- The provision of a false vaccine is imposed on article 197, 198,199 of the Health Act, article 62 of the Consumer Protection Act, Article 345 of the Law on the Eradication of Money Laundering Crime, accessed August 14, 2016, at 7.35, http://m.tempo.co.read/news/2016/0603787978/dokter-tersangka-vaksin-palsu-diduga-langgar-tiga-uu, Manufacturers of fake vaccine snared with money laundering article, accessed August 14, 2016, at 07:38, http://liputan 6.com/news/read/2575274/produsen-vaksin-palsu-dijerat-pasal-pencucian-uang, Accessed August 14, 2016, at 09.50

DICUSSION

Medicolegal Aspects

"Vaccines" and "Drugs"

Description of the vaccine, contained in the Minister of Health Regulation No. 42 of 2013 on Immunization Implementation, which defines the vaccine is an antigen in the form of dead, living but attenuated microorganisms, intact or part of which has been processed, in the form of toxoids, recombinant proteins which, when administered To someone will actively lead to specific immunity against certain infectious diseases. The word "vaccine" appears because "vaccine" is a useful element in medical care in the prevention of infection prevention by immunization. Immunization is an attempt to induce / boost a person's immunity actively against a disease, so that one day exposed to the disease will not be sick or only mild illness.

In the medicolegal study, Vaccine for immunization must have a circulation permit in accordance with the provisions of legislation. Article 15 The Regulation of the Minister of Health 42 Year 2013 on Immunization Implementation stipulates that the provision of vaccines shall be done by BUMN or Pharmaceutical Wholesalers (PBF) including importing. Controlling, monitoring and evaluation of vaccine production and distribution is carried out by the government, provincial government and government District / municipality periodically, continuously and tiered.

Given the formulation in Indonesia's regulation, the "vaccine", is present only in the Regulation of the Minister of Health, whereas in the general law terminology (KUHP), it only mentions drug products. The question that arises is whether the vaccine can be equalized with the drug, so that this product / product becomes the object of law with the same terminology.

In Guidance for Industry, the US Department of Health and Human Services[3] is mentioned:

A vaccine is an immunogen, the administration of which is intended to stimulate the immune system to result in the prevention, amelioration or therapy of any infection. A vaccine may be a live attenuated preparation of bacteria, vituses or parasites, inactived (killed) whole organism, living irradiated cells, crude fractions or purified immunogens, including those derived from recombinant DNA in a host cell, conjugates formed by covalent linkage of components, synthetic antigens, polynucleotides (such as the plasmid DNA vaccines), living vectored cells expressing specific heterologous immunogens, or cell pulsed with immunogen.

While the drug:

Drug substance is the unformulated active (immunogenic) substance which may be subsequently formulated with excipients to produce the drug product. The drug substance may be whole bacterial cell, viruses, or parasites (live or killed), crude or purified antigens isolated from killed or living cells.

Drug definitions based on Regulation of the Minister of Health No. 1010/MENKES/PER/XI/ 2008 concerning Registration of Drugs, Medicines are finished drugs which constitute the supply or alloy of materials including biological and contraceptive products, ready to be used to influence or investigate physiological or pathological systems in order Determination of diagnosis, prevention, healing, recovery and health improvement[4]. From the description, then the vaccine can be treated medicine.

3 *Guidance For Industry, Content and Format of chemistry, Manufacturing and Controls Information and Establishment Descriotion Information for a Vaccine or Related Product*, US Departement of Health and Human Service, Food and Drug Administration, 1999, hlm. 1-2

1. Medical Service Standard

Regulation of the Minister of Health No. 1438/MENKES/PER/IX/ 2010 on Medical Service Standard, Article 3 stipulates that every medical act performed by a doctor as a health service is based on National Guidelines for Medical Services (PNPK) issued by professional organizations and approved by ministers. PNPK is a reference for the making of Medical Service Standard by professional organization, and Standard Operating Procedure (SOP) stipulated by the leader of health service facility. Both become the juridical basis for the legitimacy of a medical action. Vaccine immunization health service is only done by doctor or specialist doctor.

With regard to vaccines, countries have policies on the quality of care, by applying safe injection practices to injection recipients associated with waste disposal management, to officers and the environment[5]. In the case of vaccine logistics for immunization needs, policies for the distribution and storage of products, organized and administered by the government. To

4 Meanwhile, there are other terms for the drug, namely: 1) Raw drugs: Drugs are substances that meet the requirements specified by Pharmacopoeia Indonesia or other official books established by the government. 2) Finished Medicines: Single or mixed medicines in certain dosage form: powders, liquids, ointments, tablets, capsules, pills, suppositories or other forms, and have a technical name in accordance with the Indonesian Pharmacopoeia or other books stipulated by the Government . 3) Patent medicine: A finished drug with a registered trade name on behalf of the manufacturer (manufacturer) or its authorized, and sold in original packing from the factory producing it. 4) Native medicine: Drugs obtained directly from natural ingredients (Indonesia), processed simply based on experience, and used in traditional medicine. 5) New drugs: Drugs consisting of one or a mixture of some medicinal substances as a nutritious or non-nutritious part (such as filler, solvent, vehicule) or other unknown components, so that the efficacy and safety are not known yet. 6) Generic Drugs: Generic drugs are drugs that are marketed under the name of their active ingredients with the same safety, quality and efficacy standards as innovator medicine.

5 Immunization arrangements refer to international agreements to prevent and eradicate diseases, including: international agreements on disease prevention and eradication, among others:
   1. WHO 1988 and UNICEF through the World Summit for Children in 1990 on calls to achieve immunization coverage targets 80-80-80, Elimination of Tetanus Neonatorum and Measles Reduction;
   2. UNICEF, WHO and UNFPA appeal in 1999 to achieve the target of Tetanus Tetanus and Neonatal Elimination (MNTE) in 2005 in developing countries;
   3. Appeal from WHO that countries with high endemicity> 8% in 1997 are expected to have immunized hepatitis B into routine immunization;
   4. WHO / UNICEF / UNFPA 1999 on the Joint Statement on the Use of Autodisable Syringe in Immunization Services;
   5. Convention on the Rights of the Child: Indonesia has ratified the Convention on the Rights of the Child by Presidential Decree Number 36 of 1999 dated 25 August 1990, which contains among others the right of the child to obtain basic health and wellbeing;
   6. World Health Assembly Resolution since 2012 declaring the commitment of all member states to eradicate Polio, and in 2012 it states that countries that still have transmission of polio cases must state that their country is in a state of "national public health emergency";
   7. The Millennium Development Goal (MDG) in 2003 which included goal 4: on reducing child mortality, goal 5: on improving maternal health, goal 6: HIV / AIDS combat, malaria and other diseases (accompanied by technical support from UNICEF);
   8. The Regional Committee Resolution, 28 May 2012 on Elimination of Measles and Control of Rubella, urges member states to achieve elimination of measles by 2015 and controls rubella disease;
   9. The meeting of the Ninth Technical Consultative Group on Polio Eradication and Vaccine Preventable Diseases in South-East Asia Region in 2003 to improve the process of certifying eradication of polio, reduction of measles deaths to 50% and neonatal tetanus elimination, 80% DPT3 coverage in all countries and All districts, developed strategies for safe injections and waste disposal in all countries and included hepatitis B vaccine in immunization in all countries;
   10. WHO-UNICEF in 2003 on the Joint Statement on Effective Vaccine Store Management Initiative.

overcome certain circumstances (extraordinary events) procurement of vaccines can be done with partners.

2. Criminalization in Medical Services

The forgery of the vaccine, (or let's call it counterfeiting), is a crime. But this crime is not explicitly regulated in the Criminal Code[6]. "Counterfeiting" has a link to "cheating" as set out in Chapter XXV. The provision of "counterfeiting" intends to protect the trust and truth of the object of counterfeiting, whereas in "cheating", the law provides for the protection of the community against deceptive, deceiving or empowering people[7]. The reflective questions that arise from the event of vaccine forgery law are who should be responsible and what form of accountability.

The Criminal Code is basically dualistic, it refers only to prohibited and threatened deeds with a criminal, while the person who commits a crime is not necessarily imposed with the criminal as threatened. It depends on whether in doing this act the person has an element of error, Which refers to the principle of no crime without error (geen straf zonder schuld).

The subject of crime is not just individual (recht persoon) but also corporation. Corporations can be asked for criminal responsibility with the principle of vicarious liability. In the Black laws Dictionary, vicarious liability is defined as indirect legal responsibility, for example, the liability of an employee for an employee, or a principal for tort and contracts of an agent. Vicarious liability opens a person's accountability for the actions of others. This occurs when a person has authorized the law to another person, under a terms or principle of delegation principle. For example, in the working relationship between workers and employers, the employer does not do any deed, but his subordinates then it is seen there is a mistake on the employer in the case of acts committed by subordinates[8]. The concept of strict liability and vicarious liability is based on the reality that losses incurred in corporate activity, both for individuals, communities, and the state are enormous. For example pollution and environmental destruction that occurs due to industrial waste disposal, tax evasion, misleading advertising, or the production of unsafe food and medicines for consumers.

Medical Service is a concrete legal event with distinctive characteristics. The peculiarity lies in the understanding that materially, medical action is not contrary to law if it meets the following requirements: (1). Have medical indications towards a concrete treatment objective, (2). Carried out according to the rules applicable in medical science, (3). Has been approved by the patient. Terms (1) and (2) are lege artists, derived from the standards of the medical profession. While the condition (3) is the patient's right to Informed Consent. This requirement indicates that the relationship between physician and patient is an agreement (inspection verbintenis) with this (therapeutic contract) contract, the legal basis for the patient's legal relationship with the physician meets the legality aspect, and contains legal liability binding on both parties.

Medical action is central to health care, including in vaccines. This means that the purpose of health services can only be achieved through appropriate medical action. In a therapeutic contract, medical action should only be performed after the patient receives and provides

6 The crimes of counterfeiting, generally set out in Book II of the Criminal Code, are classified as follows: false oaths (Chapter IX), counterfeit crimes of currency and banknotes (chapter X), falsification of stamp duty and branding (chapter XI), letter fraud crimes (chapters XII).

7 Adami Chazawi, *Kejahatan terhadap Pemalsuan*, Jakarta, PT. Raja Grafindo Persada, 2001, hlm.2

8 Hamzah Hatrik, 1996, *Asas Pertanggungjawaban Pidana Koorporasi Dalam Hukum Pidana Indonesia*, Jakarta, Rajawali, hlm. 13-15

Informed consent indicating that regardless of the risk of the therapeutic contract, the healthcare provider is approved for medical treatment and will not be prosecuted for any number of possible risks arising from the contract. But in reality, health care workers, especially doctors are often confronted with suspicion of a mistake in taking medical action.

Criminal Accountability under Law Number 36 Year 2009 on Health:

1). Persons or Persons (Persons) who individually have committed a criminal offense, in this case is a criminal act of counterfeiting of drugs, and the so-called sole maker (dader).

2). Corporations, which are relevant for the moment, remember that most fake drugmakers are done by business actors with big business companies, and there needs to be a legal umbrella that explicitly regulates criminal sanctions for corporate perpetrators.

In the context of medical services, all acts are based on therapeutic contracts within the realm of private law relationships. But in their implementation, this therapeutic contract becomes the object of public law when there is a "mistake" on the human body. Thus, in criminalizing the subject of law (ministry of health) there are several things that must be considered, namely: the element of scientific knowledge of research and assessment of the development of specific delays in society and the development of science and technology, international conventions, and comparisons with foreign regulations. Criminalization of health care workers should also take into account the professional qualification and competency standards, whether or not there is a violation of service standards and operational standards of a medical action[9].

Because of law. Criminal Resistance Fake Vaccine in the event that the law still cannot capture an act in the category of crime, then this approach is followed, so as to produce criminal responsibility that minimizes the potential for humanitarian degradation and justice:

a. An evolutionary approach, providing refinement, refinement, long-standing amendments to the rules (Criminal Code)

b. The global method (global approach), make its own rules outside the Criminal Code

c. The compromise approach, adding a separate chapter on specific offenses[10].

In the terminology of vaccine and drug definitions based on the substance contained therein, the "vaccine" can be categorized into "medicine", but "medicine" is not necessarily "vaccine". The study of the applicable regulation related to fake vaccines, (equivalent to "drugs") is governed in several provisions of the laws and regulations:

a. Criminal Code: Article 386 Paragraph (1) provides for the prohibition of selling, offering

9 An act can be categorized into a criminal act, or criminalized, must meet the following: 1). Ultima Ratio Principle: Criminal law is prepared as a last resort or ultimate weapon, but it is often used as primum remedium (put forward), even prioritizing penalties that can be used as funds for development in a country.2). Precision Principle: The provisions of criminal law must be precise and accurate describes a crime. The formulation of a vague and general criminal law should be avoided.3). Clearness Principl:, Criminalized action should be clearly described in the criminal law provisions, 4). Principle of Differentiation: It should be clear from one another. Avoid formulation that is global / too broad, multipurpose or all embarranging, 5) .Principle of intent: Criminalized action must be with dolus (intention), while the act of culpa (negligence) must be stated with special conditions to justify the criminalization, 6). Principle of Victim Application: The settlement of a criminal case must pay attention to the request or will of the victim. In this case the victim's interests are regulated in criminal and criminal penalties.Teguh Prasetyo, *Kriminalisasi dalam Hukum Pidana*. Bandung, Nusa Media, 2013, hlm. 41

10 Muladi dalam Teguh Prasetyo, op cit, hlm.42

or delivering drugs known to be forged, and hiding it, with a maximum imprisonment of 4 (four) years imprisonment.

b. Law Number 36 of 2009 on Health:

1). Article 196 regulates the prohibition to produce and distribute pharmaceutical preparations in the form of drugs that do not comply with the standards and/or requirements of security, efficacy or benefit, and quality in accordance with the provisions of laws and regulations, because the material that is not in accordance with the Indonesian Pharmacopoeia standards is categorized as counterfeit drugs. The crime of counterfeiting of this drug shall be punishable by imprisonment of a maximum of 10 (ten) sentences of fine of not more than Rp. 1,000,000,000.00 (one billion rupiah).

2). Article 197 regulates the prohibition of producing or distributing pharmaceutical preparations in the form of drugs that do not have distribution permit, because the drugs that are not authorized to circulate from the Government are false treats. This drug counterfeiting shall be punishable by a maximum of 15 (fifteen) years and a maximum fine of Rp. 1,500,000,000.00 (one billion and five hundred million rupiah)

3). Article 198 provides for the prohibition of any person who does not possess the expertise and authority to practice the production of drugs. Without any authority given by the Government then all drugs produced by producers are counterfeit drugs. The criminal act of counterfeiting of this drug shall be punishable by a fine of not more than Rp. 100,000,000.00 (one hundred million rupiah).

4). Article 201 regulates the subject of drug counterfeiting, that is, if the subject of a criminal act is a corporation, in the case of a criminal offense (Article 196, Article 197, and Article 198 Law Number 36 of 2009 on Health), in addition to imprisonment and penalties against The penalty, which may be imposed on the corporation in the form of a fine with a fine of 3 (three) times of the fine.

Corporations may be subject to additional criminal sanctions in the form of revocation of business license and / or revocation of legal entity status.

c. Law Number 8 of 1999 Concerning Consumer Protection, regulates:

1). Article 8 Paragraph (1) item a regulates that business actors are prohibited to produce and/or distribute drugs that do not meet the standards in accordance with the laws and regulations. Sanctions: a) Administrative sanctions in the form of prohibition to trade back fake medicinal products and in the form of withdrawal of counterfeit drugs from circulation. b) Criminal sanction in the form of maximum imprisonment of 5 (five years) and maximum fine of Rp. 2,000,000,000.00 (two billion rupiah). (2) the announcement of the judge's decision, (3) the payment of compensation for the consumer of the aggrieved drug, (4) the order of termination of certain activities causing the loss of the consumer, (5) the withdrawal obligation Drugs from circulation, or (6) revocation of production drug licenses. The regulation on penal sanctions is provided for in Article 62 Paragraph (1), and Article 63.

2). Article 19 Paragraph (1) provides for business actors to provide compensation for damages, pollution, and / or consumer losses resulting from the consumption of drugs produced or traded. The sanctions are: (1). Civil sanctions in the form of compensation, and Administrative Sanctions in the form of compensation of a

maximum of Rp. 200,000,000.00 (two hundred million rupiah) stipulated by the Consumer Dispute Settlement Agency.

The protection of the law in the paradigm of humanity in the case of fake medicolegal vaccine

Health law is a positivization of values associated with health services. In harmony with article 2 of Law No. 36 of 2009 on Health, health development is carried out by based on humanity fairness. This means that health development is wrapped in laws that provide protection based on humanitarian value. Indonesia's health law with this humanitarian paradigm means that the law upholds human dignity with the priority of protecting vulnerable people[11]. In the context of fake medicolegal vaccines, the parties involved may be in a vulnerable position. For example, patients in the presence of superior physicians in intellectual, doctors who are "oppressed" by institutional and formation programs, producers of fake vaccines are weak on economic demands, institutions that are sued by the public for social functions tarnished by cases of fake medicolegal vaccines.

The humanitarian paradigm considers that health services constructed as health businesses are inhumane deeds, degrading human dignity and contradicting justice that should be built on the side of the weak.

Moving from this paradigm then all of these components require laws that provide proper guidance.

a. For patients

The pattern of healthcare (physician) relationship with the patient is equal, of equal rank. This equality gives birth to the patient's right to receive maximum medical service. Based on Article 2 of Regulation of the Minister of Health No. 1438/MENKES/PER/IX/ 2010 concerning Medical Service Standard, medical action shall be provided on the basis of Standard Medical Service, where this standard is made in order to: provide assurance to patients for medical services based on value Scientifically in accordance with the patient's medical needs. In addition, mentioned in Article 10, in each clinical therapy, the patient receives services in accordance with Standard Operating Procedures, which include anamnesis, physical examination, diagnosis, differential diagnosis, investigation, therapy, education, prognosis.

b. For health care

Every medical action performed by the health service is based on SPK and SPO as a tool to make the action legal to the patient. SPK and SPO are created and evaluated in a new way with the support of literature and medical science and technology appraisal conducted by the Ministry of Health or institution medical education. Thus, the SPK and SPO serve as a legal protection instrument that gives normative juridical shifting every medical action. Health servants cannot be prosecuted for medical malpractice if they are in accordance with SPK or SPO.

The phenomenon of fake vaccine is also obtained in the practice of doctors, this is because there is no firmness of law enforcement in the supervision of drug dispensing practice. Patients using medical services are scattered in all places (areas) with their own complexity. The "Package" system of medicine and therapy offered by doctors on the one hand offers the ease, efficiency and effectiveness of the patient's handling, because the patient can get the

11 Yovita A. Mangesti, *Hukum Berparadigma Kemanusiaan*, Yogyakarta, Genta Publishing, hlm. 58-60

medicine cheaply and do not necessarily have to come to the pharmacy, if the distance of the pharmacy to the doctor's practice is relatively distant and time consuming. This is permissible, because in Article 35 of Law No. 29 of 2004 on Medical Practice, stipulates that physicians have the authority to store drugs in the quantities and types permitted, dispensing and delivering drugs to patients in remote areas where there is no pharmacy. In its development, this article actually provides a legal loophole for doctors to get used to providing pharmaceutical services in their own practice.

Government Regulation No. 72 of 1998 on the Safeguarding of Pharmaceutical Preparations and Medical Devices, only grants the right to pharmacies to submit drugs. The deviation of this provision is usually on the grounds of the desire to produce products with high selling value because the world of medicine is very close to the business world that has business value and profit oriented.

c. For institutions

Health services are provided in hospitals or clinics, or clinics. All acts of service refer to Law No. 44 of 2009 concerning Hospitals. The intended hospital is regularly evaluated with the Accreditation Standards, which includes the Pharmaceutical Service Standard (Regulation of the Minister of Health 58 of 2014). The Drug Management Standard is mentioned that the use of drugs in hospitals is efficiently organized to meet the needs of the patients. The assessment element is pharmacy management through a one-door system.

CONCLUSION

Based on a study of Indonesia's regulation, the regulation on vaccines is still very limited. For the case of medicolegal vaccine crime, the Criminal Code is a lex generalis, which regulates the criminal responsibility is on the subject of a person or personal crime, whereas in Law No. 36 on Health applies as lex specialist that governs criminal liability is on person or person and corporation .

In relation to the law, to be able to criminalize a health service (physician and medical), parameters of Health Service Standard and Standard Operational Procedures have been established and become the rule of law in the service of medical professionals. Legality of medical services, done on the validity of the therapeutic contract is specific and has implications for the specificity of medicolegal vaccine handling cases, this parameter must absolutely exist as a test stone whether the health care provider has committed or not committed a crime.

Law No. 8 of 1999 on Consumer Protection, criminal liability can only be applied to producers who produce and distribute counterfeit vaccines, in contracts of sale that are of a verbintentic nature. This means that, on the relationship to a therapeutic contract, it is not immediately possible to criminalize a health worker who is immunizing.

The Humanitarian Paradigm considers that health services constructed as health businesses are inhumane deeds, which have the potential to open access to degradate human dignity and human rights, as well as contrary to justice that should be built on the partisanship of the weak. The weak may be exploited patients with inadequate medical services, doctors and criminalized medical personnel, and society eroded by the health business wheel. It needs legal protection at the level of regulation and its implementation in society.

REFERENCES

Adami Chazawi.2001. *Kejahatan terhadap Pemalsuan*, Jakarta: PT. Raja Grafindo Persada,

Ahmadi Miru dan Sutarman Yodo. 2007. *Hukum Perlindungan Konsumen*, Jakarta: Raja GrafindoPersada

Amri Jusuf Hanafiah. 2009.*Etika Kedokteran dan Hukum Kesehatan*. Jakarta: Penerbit Buku Kedokteran EGC

CecepTriwibowo. 2014, *Etika Hukum dan Kesehatan*. Yogyakarta: NuhaMedika

George Kateb. 2011. *Human Dignity*, London: Harvard University Press

Hamzah Hatrik.1996. *Asas Pertanggungjawaban Pidana Koorporasi Dalam Hukum Pidana Indonesia*.Jakarta: Rajawali

Muhamas Sadi Is.2015.*Etika Hukum Kesehatan Teori dan Aplikasinya di Indonesia*. Jakarta: Prenada Media.

James Griffin.2008. *On Human Rights*,New York. New York: Oxford University Press

James Rachels. 2004. *Filsafat Moral*. Yogyakarta: PustakaFilsafat

Jusuf Hanafiah dan Amri Amir.2009. *Etika Kedokteran dan Hukum Kesehatan*.Jakarta: Penerbit Buku Kedokteran EGC

PitonoSoeparto, et.al. 2006. *Etik Dan Hukum di Bidang Kesehatan*. Surabaya: Airlangga University Press

Sofyan Lubis. 2008. *Konsumen dan Pasien dalam Hukum Indonesia*. Bandung: Liberty

Teguh Prasetyo. 2013. *Kriminalisasi dalam Hukum Pidana*. Bandung: Nusa Media

Yovita A. Mangesti. 2016. *Hukum Berparadigma Kemanusiaan*. Yogyakarta: Genta Publishing

US Departement of Health and Human Service, Food and Drug Administration, 1999, *Guidance For Industry, Content and Format of chemistry, Manufacturing and Controls Information and Establishment Descriotion Information for a Vaccine or Related Product*, USA:Rockville