

# Antiretroviral Medicine Ethical Execution Policy for HIV / AIDS Survivors in Indonesia

Aga Natalis<sup>1</sup>, Sukimin<sup>2</sup>, Tri Mulyani<sup>3</sup>

<sup>1</sup>Faculty of Law, Semarang University, Indonesia, <sup>2</sup>Faculty of Law, Semarang University, Indonesia, <sup>3</sup>Faculty of Law, Semarang University, Indonesia

## Abstract

**Introduction:** One of the health problems in Indonesia that has not been resolved is the HIV pandemic or Human Immunodeficiency Virus or a virus that attacks/infects white blood cells which causes a decrease in human immunity. To combat HIV/AIDS, treatment is performed through antiretroviral drugs. But in fact, antiretroviral drugs are often scarce which causes a decrease in the welfare of people with HIV / AIDS in Indonesia.

**Research Objectives:** This study aims to discover and analyze some policies on administering antiretroviral drugs that are fair for people with HIV/AIDS in Indonesia.

**Methods:** This study uses a qualitative method with a normative juridical approach. The data used are secondary data consisting of primary and secondary legal materials. The data was collected through a literature study and analyzed qualitatively.

**Conclusion:** In making policies, the implementation of antiretroviral drugs must be centered on PLWHA and use the PLWHA as policy actors. The policy of delivering ARV drugs that are centered on PLHIV is expected to produce fair policy outputs and then have implications for the high welfare of PLWHA in Indonesia, this is in line with the formation of a policy based on the study of responsive legal theory initiated by Nonet and Selznick. Responsive legal theory requires that the law that has implications for PLWHA, should always be sensitive to the needs of PLWHA, especially regarding the availability of ARV drugs.

**Keywords:** Policy; Antiretroviral Drugs; HIV/AIDS

## Introduction

One of the health problems in Indonesia that has not yet been solved is the HIV pandemic or Human Immunodeficiency Virus, or a virus that attacks/infects white blood cells which causes a decrease in human immunity. One of the diseases caused by HIV is AIDS or Acquired Immune Deficiency Syndrome, which is a group of symptoms that arise due to the decreased immunity caused by HIV<sup>1</sup>. There are currently 35 million people living with HIV worldwide, which

includes. 1 million women and 3.2 million aged <15 years. The number of new HIV infections was 2.1 million consisting of 1.9 million adults and 240,000 children aged <15 years<sup>2</sup>. The number of deaths due to AIDS was 1.5 million, consisting of 1.3 million adults and 190,000 children aged <15 years<sup>3</sup>.

In Indonesia, the first HIV / AIDS case was found in Bali Province in 1987. Until now, HIV / AIDS has spread in 386 districts/cities in all provinces in Indonesia. Between 2000-2018, HIV / AIDS infections declined by 37% and HIV / AIDS-related deaths by 45%, and as many as 13.6 million people survived due to the consumption of antiretrovirals (ARVs)<sup>4</sup>. This achievement is the result of the major efforts of a national HIV program supported by communities and international development partners. However, currently, 23% of people living with HIV /

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### Corresponding Author:

**Aga Natalis:**

Faculty of Law Semarang University, Arteri Soekarno-Hatta Street, Semarang City, Indonesia.

Email: aga@usm.ac.id

AIDS (PLWHA) have dropped out of ARV treatment, even though the drug can be used free of charge in hospitals and health centers in 34 provinces and 296 districts/cities throughout Indonesia. The Ministry of Health's strategy to stop the HIV / AIDS pandemic is by implementing Suluh Find Treat and Maintain (STOP), which is one of the strategies to implement Regulation of the Minister of Health of the Republic of Indonesia No. 21 of 2013 concerning HIV and AIDS Control.

Based on a report from The Joint United Nations Program on HIV and AIDS (UNAIDS), the situation for handling HIV in Indonesia is still far from qualified, it is even one of the worst in Asia-Pacific. Although the government already has a special HIV prevention program, the annual rate of infection is still quite large. One of the reasons why handling HIV in Indonesia is still far from qualified is related to the scarcity of ARV drugs. ARV drugs are scarce in 40 districts and cities in Indonesia<sup>5</sup>.

Based on records from the NGO Indonesia AIDS Coalition (IAC), this crisis of drug stocks has occurred several times in the last 2 years without any concrete solution from the Ministry of Health. The State Revenue and Expenditure Budget (APBN) which has been allocated for the purchase of ARV drugs, cannot be executed because the system and mechanism for drug procurement is inefficient, this is because the process of procurement of ARV drugs for Fixed-Dose Combination types of TLE was declared failed in 2018, so the allocation of APBN funds cannot be channeled to buy these drugs. The drug tender failed because PT Kimia Farma did not agree with the price offered by the Ministry of Health (Kemenkes). A limited auction process with participants from PT Kimia Farma and PT Indofarma Global Medika was then carried out, but it did not bring out any winners.

The failure of the tender process for ARV drugs resulted in the TLE type of Fixed-Dose Combination being increasingly difficult to find in several cities in Indonesia. Based on data compiled by IAC, the relatively safe drug availability status is only found at Ananda Bekasi Hospital and Elisabeth Bekasi Hospital. Meanwhile, in several other hospitals in Jabodetabek, Central Java, Deli Serdang, and Makassar, Palembang and Medan majorly were recorded as empty. Besides that, there are still several hospitals that are noted to have limited availability, or only provide in splits. This situation endangers the health of people living with HIV

as well as undermines efforts to stop the epidemic and discredits efforts to optimize the process for procuring essential medicines, especially ARVs. From previous problems, this study aims to identify and analyze policies on administering antiretroviral drugs that are fair for people with HIV / AIDS in Indonesia.

## Research Methodology

This study uses a qualitative research method with a normative juridical approach. The normative juridical approach method is a study of the principles of positive law written in the constitution and conceptualizing law as a written rule. This research is focused on studying and researching legal material, namely the policy of administering antiretroviral drugs to later criticize it to achieve a model for administering fair antiretroviral drugs for people with HIV / AIDS in Indonesia. The data used in this research is secondary data. The secondary data consists of primary legal materials and secondary legal materials<sup>6</sup>. The primary legal materials referred to are all laws and regulations related to the administration of antiretroviral drugs, particularly Law Number 36 of 2009 concerning Health. The secondary legal materials used are journals, books, or research related to the title of this research. Secondary data is collected through literature study and will be analyzed qualitatively.

## Discussion

Article 1 Number 8 of Law 36 of 2009 concerning health defines medicine as a material or material guide, including biological products, used to influence or investigate physiological systems or pathological conditions in the context of determining a diagnosis of prevention, cure, recovery, health improvement and contraception for humans. Article 8 stipulates that every person has the right to obtain information about his / her health data, including the actions and treatments that he has or will receive from health workers. Based on Article 36, the government guarantees the availability, equity, and affordability of medical supplies, especially essential medicines. In ensuring the availability of these emergency medicines, the government can implement special policies for the procurement and utilization of drugs and medicinal substances.

One of the drugs in Indonesia that is quite important today is antiretroviral drugs (ARV). ARVs work directly to block HIV replication. ARV therapy aims to reduce the amount of virus in the blood to low or below detectable levels for a long period. Currently, there are three classes

of ARVs available in Indonesia, including<sup>7</sup>:

1. Nucleoside Reverse Transcriptase Inhibitor (NRTI): this drug is a nucleoside analog that blocks the process of converting viral RNA into DNA. Included in this class of drugs are zidovudine (ZDN. AZT), lamivudine (3TC), didanosine (ddl), zalcitabine (ddC), stavudine (d4T), and abacavir (ABC);

2. Non-nucleoside Reverse Transcriptase Inhibitor (NNRTI): including this class of drugs are nevirapine (NVP), and delavirdine (DNL); and

3. Protease Inhibitor (PI): works to inhibit the protease enzyme which cuts long chains of amino acids into smaller proteins. These include indinavir (IDV), nelfinavir (NFV), saquinavir (SQV), ritonavir (RTV), amprenavir (APV), and lopinavir/ritonavir (LPV).

The provision of ARVs in Indonesia is based on the Regulation of the Minister of Health of the Republic of Indonesia Number 87 of 2004 concerning Guidelines for Antiretroviral Treatment. Antiretroviral treatment based on Article 1 of this ministerial regulation is part of HIV / AIDS treatment to reduce the risk of HIV transmission, inhibit the worsening of opportunistic infections, improve the quality of life of HIV sufferers, and reduce the amount of viral load in the blood until it is undetectable.

Antiretroviral treatment is given to HIV patients aged 5 (five) years and over who have shown clinical stage 3 or 4 or CD4 T lymphocyte counts are less than or equal to 350 cells / mm<sup>3</sup>; pregnant women with HIV; babies born to mothers with HIV; HIV sufferers, infants or children less than 5 (five) years old; HIV sufferers with tuberculosis; HIV sufferers with hepatitis B and hepatitis C; people with HIV in key populations; HIV sufferers whose partners are negative; and HIV sufferers in the general population living in areas of the HIV epidemic.

Antiretroviral treatment can be given comprehensively with the treatment of opportunistic infections and comorbidities and other supportive treatment as needed. Antiretroviral treatment starts from a hospital that is at least class C and can be continued at a health center or other health care facility that can treat antiretroviral drugs. In blood with widespread and concentrated HIV epidemic levels, antiretroviral treatment can be started at a health center or other health care facility that has antiretroviral treatment capability

and is excluded from antiretroviral treatment given to infants and children less than five years of age.

Guidance and supervision of the implementation of this Ministerial Regulation is carried out by the Minister, provincial government, and district/city government by involving professional organizations by their respective duties and authorities.

The Ministry of Health through the Directorate General of Disease Control and Environmental Health has launched the Care, Support, and Treatment (CST) Program for people living with HIV-AIDS (PLWHA) starting in 2004 with training for 25 Antiretroviral Referral Hospitals, which is also a referral hospital for the treatment of PLWHA. The determination of the ARV Referral Hospital was through the Decree of the Minister of Health. With the increasing number of cases, until 2011, 278 ARV Referral Hospitals have been established, by Decree of the Minister of Health Number 782 / Menkes / SK / IV / 2011.

The procurement of ARV drugs is still concentrated at the Ministry of Health and is currently fully subsidized by the government. The distribution is still centralized and sent directly to the services that need it according to service requests. This concentration is carried out to facilitate monitoring of drug use and availability in services, given the characteristics of the disease and the consumption of specific ARV drugs, where the drugs must be consumed on time and for life.

The budget for the procurement of ARVs has been allocated in the APBN and a grant from the AIDS Component Global Fund for AIDS, TB, and Malaria (GF-ATM). The budget with the State Budget (APBN) is increasing every year. In 2011, the comparison with GF-ATM funds was 70:30. It is hoped that next year it will get even bigger and in the end, the need for ARV can be met entirely with APBN funds.

The procurement process with APBN funds is carried out by the Directorate General of Pharmaceutical and Medical Devices through Electronic Procurement Services (LPSE), while the budget with GF-ATM funds is through the Voluntary Pooled Procurement (VPP) procedure, where the Ministry of Health submits the needs to the GF-ATM central procurement. Then they will buy directly from the drug factory. In this way, quality drugs are obtained at the cheapest price (breaking the trade chain). In the specifications for the procurement of ARV drugs, it is always stated that the

expiration period of the drug is at least 18 months since the drug is received by the goods receipt committee.

APBN funds are used to purchase first-line ARVs and a small portion of second-line ARVs, while GF-ATM funds are used mainly to buy second-line ARVs and some of the first-line ARVs that cannot be produced domestically, such as ARV for children and the combination of stavudine + lamivudine.

To cut delivery times, currently, there is a decentralization of ARV distribution in several provinces that are considered capable, in terms of human resources and infrastructure. The province that has implemented it is East Java. Provinces that have just started are Bali, Papua, and West Java.

In brief, the flow of drug delivery in the decentralized province is as follows: Every month the hospital reports on drug use and drug requests using the monthly report form. The amount of medicine demanded is the need for 1 month and 2 months of reserve stock by considering the final stock. So that the hospital has to be willing to supply medicine for 3 months. Every month the hospital reports on drug use and drug requests using the monthly report form. The amount of medicine demanded is the need for 1 month and 2 months of reserve stock by considering the final stock. So that the hospital must have a supply of drugs for 3 months. Reports are addressed to the Provincial Health Office. At the Provincial Health Officer, the request will be responded to by verifying drug calculations and making a Pre Order to the Provincial Kimia Farma to send the requested drug to the service. This process will take a maximum of 5 days. Kimia Farma Provinsi every 3 months submit a request for drug stock based on the calculation of the request from the service to Kimia Farma Pusat. The Provincial Health Office sends a copy of the report from health services to the Sub-Directorate for AIDS & Sexually Transmitted Diseases, Directorate General of Disease Control and Environmental Health.

After receiving new drugs, both domestically produced and imported through the above mechanism, the Ministry of Health directly distributes ARVs to all referral hospitals. Availability of drugs depends on reports of use and requests for drugs from the designated referral hospital. With the supervision mechanism and the pattern of procurement and distribution of ARVs, it is hoped that there will be no longer the administration and use of ARV drugs that have expired.

What should also be emphasized to the public is that ARV drugs only reduce the amount of HIV circulating in the blood and do not cure the disease. ARV drugs must be taken every day at the right dose and time and continue to be taken for life. Non-adherence to taking ARVs can lead to resistance.

HIV / AIDS prevention policies, especially concerning the provision of antiretroviral drugs, are largely determined by the government's perspective on HIV / AIDS. However, the government is considered not to be siding with PLWHA regarding HIV / AIDS prevention efforts because the availability of antiretrovirals, which is often limited, causes a decrease in the welfare of PLWHA.

Regarding the procurement of antiretroviral drugs that are equitable for PLWHA, it can refer to the perspective of the welfare state law. As stated by Satjipto Rahardjo, the most serious problem when talking about problems of the state and justice is about the 'culture' of community happiness (community welfare). In the form of a question, it will read, "state for what?" and answer with "the state to make the community happy (welfare of society)". From this opinion, it can be concluded that the aim of the modern state is none other than to bring about happiness, prosperity, and human glory<sup>8</sup>.

The birth of the concept of a modern state as a mission to realize the welfare and happiness of society is marked by the development of a concept of a 'law state', namely a social service state (welfare state). Such a rule of law has a duty as a public servant, namely to organize and strive for justice / social welfare which Lemaire calls *bestuur zorg*. The concept of a welfare law state is the result of the development of the *polizeistaat* law state concept and the national law state concept<sup>9</sup>. This understanding of the rule of law is contained in the 4th paragraph of the Preamble to the 1945 Constitution of the Republic of Indonesia (UUD NRI 1945), that one of the objectives of the Indonesian State is to advance public welfare<sup>10</sup>.

Based on the concept of the welfare state law, some of the obligations that must be done by the state are to fulfill, provide, serve, and protect its citizens. All of these are then reduced and introduced in the concept of Human Rights, in the form of rights to be free from and free to<sup>11</sup>. One of the manifestations of human rights referred to is the right to health, as regulated in Article 28 H paragraph (1) of the 1945 Constitution of the

Republic of Indonesia, which states that everyone has the right to live in physical and mental prosperity, to live, and to have a good and healthy living environment and the right get health services. The guarantee of the right to health is also contained in Article 12 paragraph (1) of the International Convention on Economic, Social and Cultural Rights established by the United Nations General Assembly 2200 A (XXI) dated December 16, 1966, namely that states participating in the convention recognize the right of everyone to enjoy the highest attainable standard of physical and mental health<sup>12</sup>.

Efforts that can be made by the government to realize the right to health for its citizens are by carrying out various activities to maintain and improve the highest public health status, which is then carried out based on the principles of non-discrimination, participatory and sustainable development in the framework of the formation of Indonesian human resources, as well as increasing the resilience and competitiveness of the nation for national development. Further regulation of the right to health is contained in Article 13 of Law Number 36 Year 2009 concerning Health, one of which is that everyone has the same rights to gain access to resources in the health sector. The government's responsibility regarding the rights of citizens is stated in Article 15, that the government is responsible for the availability of the environment, structure, health facilities, both physical and social, for the community to achieve the highest health status.

Medicine is an important component in health care. Limitations of drugs will certainly cause health facilities to be less than optimal in carrying out their duties, namely serving the community<sup>13</sup>. ARV is the life of PLWHA, the scarcity of ARV is endangering the health of PLWHA, undermining efforts to stop the pandemic and discrediting efforts to optimize the process of procuring essential drugs, especially ARV. PLWHA are also citizens whose rights must be fulfilled and protected by the state. When issues of health and medicine are made commodities and government policies tend to be discriminatory, the rights and needs of PLWHA will be threatened, therefore the government is obliged to form a policy for administering ARV drugs that is just for PLWHA.

David R. Holtgrave in his book "Handbook of Economic Evaluation of HIV Prevention Programs"<sup>14</sup>, said that discrimination against PLHIV, especially in any government policymaking, must be immediately

overcome, because discrimination will affect the quality of life of PLHIV in society, therefore every policy-making especially concerning PLWHA, in this case, the policy for administering ARV drugs needs to apply the principles of good governance. In a good governance perspective, policymakers are required to produce policies that lead to the goals of political philosophy, so that they can be ethically justified, for example, policies carried out without discrimination. A policy will lose its ethical value if it is carelessly disregarding the interests of the lives of many people. In the Cochran and Malone category, a policy is interpreted as a good policy, if the policy is related to government decisions and actions designed to save people's problems, in this case, PLWHA<sup>15</sup>.

Following the principles of good governance, policies can be formed based on the philosophy of feminism. The influence of feminism in the study of legal science is known as the feminist legal theory which focuses on legal reasoning to reach a certain conclusion, feminists will consider things that are not universal, not general, but rather reflect women as a part that does have certain needs and uniqueness. starting point of reasoning<sup>16</sup>. Feminism develops specific legal arguments that pose challenges to discriminatory and unfair laws<sup>17</sup>.

Feminist legal theory considers that good law is law that sided with women and of course anyone including PLWHA as a minority group is often socially weakened by various government policies, laws based on feminist studies must be based on the objective of fighting oppression, domination and discrimination. . Departing from the principles of good governance and feminist legal theory, the policy of administering ARV drugs for PLHIV must be formed based on the principle of minority-centered social policies, that in public policy PLWHA is not only positioned in the target group but rather social actors who can determine and fight for their rights. , especially the right to good health through public policy. PLWHA in the process of making public policies must be given several rights, for example, the right to existence and the right to freedom of opinion and to be critical in making a public policy. The right to freedom for PLWHA in policy-making must be carried out by government officials, this is following the provisions in Article 7 paragraph (1) letter f of Law 30 of 2014 concerning Government Administration, that government officials are obliged to provide opportunities for citizens to be heard before their opinion. Make

decisions and/or actions following the provisions of laws and regulations<sup>18</sup>.

The policy for administering ARV drugs that are centered on PLHIV must respect the rights, needs, and voices of PLWHA. The policy of delivering ARV drugs that are centered on PLWHA is expected to produce a fair policy output which then has implications for the high welfare of PLWHA in Indonesia, this is following the formation of a policy based on the study of responsive legal theory initiated by Nonet and Selznick<sup>19</sup>. Responsive legal theory which requires that laws that have implications for PLWHA should always be sensitive to the needs of PLWHA, especially regarding the availability of ARV drugs. Based on the study of responsive legal theory, the policy of administering ARV drugs must be oriented towards justice which is more than just procedural justice, but emphasizes substantial justice. Such a policy model is following the objectives of the state set out in the Preamble to the 1945 Constitution of the Republic of Indonesia, namely to promote public welfare.

### Conclusion

The fair administration of antiretroviral drugs for people with HIV / AIDS in Indonesia, that Law 36 of 2009 concerning health stipulates that every person has the right to obtain information about his / her health data, including actions and treatments that have been or will be received from health workers. Based on Article 36, the government guarantees the availability, equity, and affordability of medical supplies, especially essential medicines, including antiretroviral drugs for people with HIV / AIDS. HIV / AIDS prevention policies, especially those related to the provision of antiretroviral drugs, are largely determined by the government's perspective on HIV / AIDS. However, the government is considered not to be siding with PLWHA regarding HIV / AIDS prevention efforts because the availability of antiretrovirals, which is often limited, causes a decrease in the welfare of PLWHA. Departing from the principles of good governance and feminist legal theory, the policy of administering ARV drugs for PLHIV must be formed based on the principle of minority-centered social policies, that in public policy PLWHA is not only positioned in the target group but rather social actors who can determine and fight for their rights. , especially the right to good health through public policy. PLWHA in the process of making public policies must be given several rights, for example, the right to existence and the

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