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# Drug Regulation in Self Medication Trini Handayani<sup>1</sup> and

## Abstract

One of the important component of Human Development Index (HDI) is health index. Health is one of the most important aspects of human life. The health index is used to assess the condition of public health, the improvement of the health index will also have an impact on HDI. Self-medication is literally a treatment that is performed by a person him/herself in the absence of the need to expend much money and effort as well to visit a practitioner. In another words, an individual can purchase an Over the Counter medicine to treat their own disease. If it is done properly, self-medication can bring a huge advantage to the individual him/ herself as they can address their disease by applying the correct amount of dose and type of medicine. To conceive the behavior of the respondents, a direct interview method is used by interviewing several citizens. The interview result indicates that 97% people in West Java have performed self-medication. Drug regulation is a public policy that restricts private-sector activities to attain social goals set by the State.

Keywords: Health index; Self-medication; West java

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## Introduction

Drugs are not ordinary consumers' products. In most instances, consumers are not able to make decisions about when to use drugs, which drugs to use, how to use them and to weigh potential benefits against risks as no medicine is completely safe. Professional advice from either prescribers or dispensers are needed in making these decisions. However, even healthcare professionals (medical doctors, pharmacists) nowadays are not in capacity to take informed decisions about all aspects of medicines without special training and access to necessary information. The use of ineffective, poor quality, harmful medicines can result in therapeutic failure, exacerbation of disease, resistance to medicines and sometimes death [1].

Nanoparticles govern an all-important role, currently, in determining the tissue distribution of either hydrophobic or hydrophilic anti-cancer drugs by encapsulating them or by covalent attachment [2]. Different types of nanoparticles exhibit different variations in their composition, structure and surface morphologies thus making them ideal candidates for drug delivery with their own specific advantages and accompanying limitations [3]. Nanotechnological research has come a long way in the past decade, with major advances being made, both in terms of diagnostic and therapeutic potential of nanoparticles [4]. Nanoparticles will be able to deliver a precise dose of the

# Dwidja Priyatno<sup>2\*</sup>

- 1 Suryakancana University, Indonesia
- 2 Bandung Law School, Indonesia

#### \*Corresponding author: Priyatno D

dwidjapriyatno@yahoo.co.id

Bandung Law School, Indonesia.

Tel: +62 263 270106

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drug in the tumor region due to the enhanced permeability and retention effect [5]. General features of the tumors include leaky blood vessels and extremely poor lymphatic drainage. Free drugs are known to diffuse non- specifically; however, nanoparticles accumulate at the specific target site with the enhanced permeability and retention effect. Effective cancer therapy always necessitates a sound understanding of cancer pathophysiology [6].

Nanocarriers, when presented in the colloidal form, have afforded utmost advantages over conventional delivery systems. These possibilities are not devoid of challenges, but by and large, various research activities [7].

Successful ushering of nanomedicine has shown immense potential in advancing cancer treatment regimens. The unique characteristics of nanoparticles such as their optimal size, shape, efficient surface to volume ratio, surfaces that can be optimally tailored make them very attractive delivery candidates for highly hydrophobic chemotherapeutic agents. Moreover, their inherent capacity to encapsulate these drugs and enhance their solubility profiles offers them unique advantages over conventional treatments [8].

Polymeric micelles are core-shell structures synthesized from amphiphilic block copolymers. Various conventional characteristics of these polymeric micelles such as increasing the solubilization of poorly hydrophobic drugs [9]. The utilization of polymeric micelles in providing optimal drug delivery against cancer has been thoroughly investigated and exhibits many promising facets, as evidenced by many research scientists all over the globe. The acceleration in the rapid development of these micelles as a robust delivery platform is primarily dictated by the fate of these micelles *in vivo*, which ultimately govern their stability profile and efficacy in the blood stream [10]. In recent years, polymeric micelles have attracted a lot of attention in terms of their specific delivery of hydrophobic cargo to the target site. polymeric micelles are considered more stable than their surfactant counterparts and can prolong circulation times *in vivo* and their specific accumulation in the tumoral tissues [11].

Medicine has evolved gradually over the time with renewing their quality time by time. For example, Mithridates VI (120 BC), King of Pontus, concocted a compound preparation called "Mithridatium" which included 41 individual components and was held as a panacea for almost all diseases until the late 1780s. It took until 1540 when in England the manufacture of Mithridatium and other medicines was subjected to supervision under the Apothecaries Wares, Drugs and Stuffs Act. The Act was one of the earliest British statutes on the control of medicines and it established the appointment of four inspectors of "Apothecary Wares, Drugs and Stuffs". This could be the start of pharmaceutical inspections. The modern medicines regulation started only after breakthrough progress in the 19<sup>th</sup> century life sciences, especially in chemistry, physiology and pharmacology, which laid a solid foundation for the modern drug research and development and started to flourish after the second World War. Unfortunate events have catalyzed the development of medicines regulation more than the evolution of a knowledge base. In 1937 over 100 people in the United States died of diethylene glycol poisoning following the use of a sulfanilamide elixir, which used the chemical as a solvent without any safety testing. This facilitated introduction of The Federal Food, Drug and Cosmetic Act with the premarket notification requirement for new drugs in 1938. However, in countries with poor regulatory environment even recently medicines contaminated with diethylene glycol have killed patients [12].

Drug regulation is a public policy that restricts private-sector activities to attain social goals set by the State. Drug regulation is the totality of all measures 2 legal, administrative and technical I which governments take to ensure the safety, efficacy and quality of drugs, as well as the relevance and accuracy of product information. Public health and safety concerns have obliged governments to intervene in the activities of the pharmaceutical sector. Although drug regulation is basically a government function, regulatory activities can also be carried out by private organizations, if they have been granted authorization by the agency whose own authority is granted by law. Equally, the government may choose to apply the same regulatory requirements to government-owned facilities as to those in the private sector. For instance, the same good manufacturing practice (GMP) standards can be applied to both government and private manufacturers. Self-regulation also occurs, in which members of the group targeted for regulation organize some means of mutual control among themselves [13].

Self-medication is defined as "the use of drugs to treat selfdiagnosed disorders or symptoms, or the intermittent or continued use of a prescribed drug for chronic or recurrent disease or symptoms" [14]. Appropriate self-medication can cure diseases, saving time and money which would be spent on visiting doctors and even it can sometimes save the patient's life in acute conditions [15]. Self-medication itself in this case is limited only to modern medicines, those are Over the Counter (OTC) medicine and limited OTC medicine. The benefits of using OTC and limited OTC medicine are: safe if consumed according to the instruction; effective to reduce the grievance, since 80% of the illness grievances are self-limiting; cost-efficient; timeefficient; take a main role in determining the therapy decision; and reduce the burden of the government because of the limited medical staffs and health facility among the society [16].

Considering the research that is done by Supardi and Notosiswoyo, the knowledge regarding the treatment itself is mostly poor and people awareness to read the label attached to the medicine package is also low. The demographic characteristics associated with such use, the types of drugs used, the sources of selfmedication, the symptoms for which the drugs were reportedly used, and duration of use were also examined [17]. The main information source to do self-medication generally comes from mass media. Some of the information come from medicine factory are not educating people, in fact even incorrect. Supardi states that the factor that causes the behavior of self-medication the most is still unknown. Nevertheless, according to the result of Worku and Abebe research found that in accordance with sociodemographic factor such as age, gender, and income, people who perform self-medication the most belong to the group of under-30 age (59.5%), woman (61.9%), and high-income party (40.5%).

Nearly all drugs have potential for adverse drug reactions, hence there is always an imminent need to analyze the risk-benefit analysis and the overall ratio for prescribing the efficacious dose. The severity of these adverse drug reactions always varies as per age, gender, existing conditions, socioeconomic differences, dosage regimens to name a few.

These adverse drug reactions can be broadly classified into 3 different categories:

- **1. Idiosyncratic:** These are generally not dose-related or allergic. They occur in a smaller proportion of patients.
- **2. Allergic:** These are generally not dose-related and require previous exposure. After a patient is sensitized due to the drug acting as a primary allergen, further repeated exposure produces this allergic reaction.
- **3. Dose-related:** This is a common occurrence for drugs with a very narrow therapeutic index [18].

## **Materials and Methods**

The method of research uses the mixed method. For the first, the

object research in quantitative method and the result of research would be analyzed in qualitative method. The research is carried out on the communities located in West Java Indonesia. The main reason of why the location of the research location is in West Java is because it is a location where almost all the counties are villages or rural areas and the distance of the research location to the center of Indonesia, which is Jakarta, is relatively close. West Java has a tiny ratio of the number of drugstores to the number of societies so that many small shops, called warung, sell medicines. There are 3.454 drugstores in West Java, while the area is 35.377,76 km<sup>2</sup>. The ratio of drugstore to the total population in West Java is 46.709.569: 3.454 or 1: 13.523 more. This ratio shows that the number of drugstores is insufficient. Meanwhile according to Indonesia's Ministry of Health, the ideal ratio of drugstores to the total population is 1: 10,000.

#### **Research instrument**

Materials and data source in this research is questionnaire. Prior to the creation of the questionnaire metrics, Focus Group Discussion (FGD) is performed on several society groups outside the research respondent to delve more information about selfmedication that has been performed among the society. The data collection is done by using questionnaire metrics developed by researcher. Questionnaire consists of several question sections, those are respondent identity, self-medication behavior, question that correlates with proper medicine, dosage, and polypharmacy.

#### **Implementation procedure**

This research is implemented by giving questionnaire to the respondent. 134 samples were taken. Those samples consist of students, university students, lecturers, staffs, and patients who visited private general practitioner. The inclusion criteria in determining the sample is that the sample is not a medical staff, not illiterate, performing his/her own medication based on the illness, and using medicine that comes from the drugstore or small shop.

## Results

Self-medication is beneficial in treating mild disease only if performed properly and rationally based upon ample knowledge of the used medicine and the ability to identify the disease or arisen symptoms. Not only is a haphazard self-medication a waste of time and money, but also harmful.

The advantages of the self-medication itself are safe if used according to the instruction; effective to diminish grievance since 80% of illness is self-limiting, that is cured itself even without any medical staff intervention; cost of purchasing medicine is relatively low than using medical service; cost-efficient as it does not need to visit medical facility; the feeling of satisfaction appear as the performer takes a main role in therapy decision; taking part in medical service system; avoiding shame or stress if he/she needs to show several body parts to the medical staff; and helping government to overcome the lack of medical staff among society. As for the shortcomings of self-medication are the medicine can actually endanger one's health if it is not used properly according to the instruction; waste of time and money when it is used erroneously; there is a likelihood that an unexpected reaction of the medicine will emerge, for instance sensitivity, and side effect or resistance; an amiss usage of medicine as the result of sketchy information from medicine advertisement; ineffectiveness of the medicine caused by incorrect diagnosis and medicine choice; and lastly it is hard to act objectively because the medicine choice is influenced by experience of using the same medicine in the past and his/her social environment [19].

Medical treatment resource in Indonesia, according to Kalangie covers 3 sectors that associates each other, those are selfmedication, traditional medication, and professional medical medication. In treating illness, someone can choose one to five medication resources, however the first action that is mainly chosen is to self-medicate. The standard that is used to choose the medication resource, in accordance with Young, is the knowledge regarding diseases and their treatment, a confidence of medicine/medication, the severity of the disease, affordability, and the distance to the medication source. Among those 4 standards, the severity of the disease is the most dominant factor. The process of decision making to choose the medication resource begins with receiving information, processing many possibilities and its impact, decision making by considering from all the available alternatives. A person's interpretation of a disease may vary so as it affects one's decision. For example, the feeling of sluggish while waking up can be interpreted as exhaustion by someone who has worked hard, influenza symptoms on cloudy weather, or severe disease on a chronic illness patient. Different interpretation results in different choice of medication resource. To overcome toddlers' illness, the society in a village of Central Java Province opts for self-medication to treat mild disease, visits paramedic or medical staff for a middle severity disease and visits traditional healer for a severe illness.

Observing Peraturan Menteri Kesehatan No. 919/MENKES/ PER/X/1993, (Indonesia Ministry of Health's Regulation) standards of medicine that can be served without using prescription are:

- 1. No contraindication for a use on a pregnant woman, a child under 2 years old, and an elderly above 65 years old.
- 2. Self-medication using medicine is intended not to add any risk for a continuous disease.
- 3. The use of it needs no specific procedure or tool that needs to be executed by medical staff.
- 4. The use of it is required for a high prevalence disease in Indonesia.
- 5. The intended medicine owns a safe efficacy ratio which can be held responsible for a self-medication action.

The followings are the types of medicines according to the usage:

1. Without physician prescription

Non-limited OTC medicine marked by black circle, green base.

Limited OTC medicine marked by black circle, blue base.

- 2. Obat Wajib Apotek (OWA) is a hard drug without prescription marked by black circle, red base;
- 3. Meal supplement

Many articles reported that common OTC and Prescription Only Medications (POM) have been associated with adverse health reactions or fatalities. In addition, self-medication can slip towards medication with POM and Controlled Drug Prescription Only Medicines (CD-POM). This inappropriate use may result in irrational medicine use, delayed seeking medical advice, increased side effects and drug interactions [20,21].

Several studies investigating self-medications have revealed the use of sub therapeutic doses and frequent use of antibiotics and other POM. Self-medication is influenced by many factors such as education, gender, socioeconomic status and availability of medicines. A study was conducted in Khartoum state, Sudan to estimate the prevalence of self-medication with antibiotics/ antimalarial concluded that the self-medication is alarmingly high where 73% of the population reporting to have used such medicines. Given the growing global resistance for antibiotic and the documented health related issues to inappropriate use of such medicines. This has major impact on public health and implications of health policies for countries like Sudan [22].

The table result of 120 respondents shown that 116 respondents preformed self-medication, and the rest which are 4 respondents said that they never done self-medication.

Based on **Table 1**, most of the respondent is a woman, under 30 of age, have low education, un employee, and lived in city.

Based on **Table 2**, nearly all the respondent performed selfmedication with 97%, with 31% of the performed self-medication using ethical drugs that need medical doctor prescription, and there is respondent that using 2 or 3 kinds of medicines at once, the rest there are respondent that still take on 2 drugs with same purpose.

The provisions in Article 17 paragraph of Regulation of the Minister of Health No. 9 of 2017 on pharmacies, pharmaceutical supply suppliers, medical devices and medical consumables in accordance with the provisions of laws and regulations. The pharmaceutical preparations in question are medicines, medicinal materials, traditional medicine and cosmetics, the provisions of article 1 number 11.

Variable	Total	Percentage (%)	
Gender			
Woman	70	58	
Man	50	42	
Age			
<30	84	70	
≥ 30	36	30	
Education			
High (graduated from University)	49	41	
Low (graduated from high school)	71	59	
Occupation status			
Employee	45	38	
Unemployee	75	62	
House location			
Rural	58	48	
City	62	52	

#### Table 1 Characteristic of west java respondents.

Variable	Total	Percentage (%)	
Self-medication			
Performed	116	97	
Never	4	3	
Types of medicine			
OTC	107	89	
Ethical	37	31	
Traditional	16	13	
Multidrug (≥ 2 medicine)	38	32	
Polypharmacy			
Yes	3	3	
No	113	97	

Table 2 Distribution of self-medication of west java.

G drug listings by pharmacists or other pharmacists are illegal. In health legislation, which reads every person producing or distributing pharmaceutical preparations that do not meet the standards, criminal penalty and imprisonment.

Government Regulation Number 51 of 2009 expressly sternly demands hard drugs (ethical) must be accompanied by a doctor's prescription and submitted by a pharmacist.

The Government has an obligation to exercise oversight of irresponsible acts, in accordance with the provisions of Article 98 paragraphs refers that the Government is obliged to foster, regulate, control the procurement, storage and distribution of pharmaceutical preparations and medical devices. Demand for people who do self-medication using drug list G, pharmacies should not have the authority of submitting drug list G accompanying prescription dentist.

WHO is the directing and coordinating authority for health within the United Nations system? It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidencebased policy options, providing technical support to countries and monitoring and assessing health trends. In the 21<sup>st</sup> century, health is a shared responsibility, involving equitable access to essential care and collective defense against transnational health threats.

WHO's role in drug regulation is fourfold. First, issuing necessary norms and standards (see examples above) through its Expert Committees (such as World Health Organization Expert Committee on Specifications for Pharmaceutical Preparations and World Health Organization Expert Committee on Biological Standardization) and Expert Committee like bodies (such as International Nonproprietary Names Expert Group and International Working Group for Drug Statistics Methodology - issuing Anatomical, Therapeutic and Chemical or ATC codes and Daily Defined Doses or DDDs for drug utilization research). Second, supporting regulatory capacity building leading to implementation of drug regulation on national level and its harmonization on regional and Global level. This activity involves assessment of regulatory activities on country level and various technical training courses (such as GMP and GCP, how to assess generic medicines, bioequivalence, safety monitoring and

pharmacovigilance, quality assurance and quality control) and customized technical assistance (in cooperation with numerous WHO collaborating centers and other partners) to the countries. Third, in selected areas of essential products, ensuring the quality, safety and efficacy of limited high public health value essential medicines (such as antiretrovirals to treat HIV/AIDS, or medicines to treat malaria) and vaccines (used in national vaccination programs) through "prequalification". De facto prequalification, although primarily meant for UN procurement and international donors, is a regulatory activity mimicking medicines registration (marketing authorization) in its all elements to ensure that products pregualified meet all international standards for quality, safety and efficacy. Prequalification program has also a very strong capacity building element built into it. Fourth, WHO plays a very important role in facilitating exchange of regulatory information for which it has developed several tools. Since 1980 WHO convenes every second year International Conference of Drug Regulatory Authorities (ICDRA) and publishes their proceedings. These conferences provide drug regulatory authorities of WHO Member States with a forum to meet and discuss ways to strengthen collaboration. The ICDRAs have been instrumental in guiding through its recommendations regulatory authorities, WHO and interested stakeholders and in determining priorities for action in national and international regulation of medicines, vaccines, biomedicines and herbals [23].

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# **Discussion and Conclusion**

The Respondent still using ethical medicine that needs prescription by medical doctors to get the medicine. According to regulation of the Minister of Health No. 9 of 2017 on pharmacies, the pharmacist cannot give the ethical medicine without medical doctor prescription. Based on case in West Java, the respondent came to pharmacy to get the ethical medicine without prescription and the pharmacist just give the medicine to the patient.

## Recommendations

Self-medication that has been performed by some of the society is permitted under several circumstances. Nevertheless, there are limitations that need to be taken care of to prevent and to avoid unexpected side effects. On the next occasion, this research should be extended as following:

- 1. Advertised of medicine knowledge to community about the drug regulation, which types of medicine that cannot be consumption without medical doctor prescription.
- 2. Conduct fostering to the pharmacist organization not to give the ethical medicine to the patient without medical doctor's prescription.
- 3. Build application about the assurance of self-medication and the danger of self-medication if we used it away.
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