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Research Article

### **Ethics in the Pharmaceutical Business**

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# Abstract

This paper discusses the pharmaceutical industry which is an important complement in the hospital sector. Without medicine, hospitals will find it difficult to carry out activities. Interestingly, the behavior of the pharmaceutical industry actually refers to maximize profits. This behavior certainly enters the hospital sector which is a sector with a social tradition of humanity. In this case the question is, are there ethical considerations in the pharmaceutical industry that maximize profits? In the health sector, the pharmaceutical industry has a big influence on hospitals and various health care organizations. The amount of drug turnover can reach 50%-60% of the hospital budget. Medicine is an important part of the hospitals, doctors, and patients. Therefore. it is necessary to understand the behavior of the pharmaceutical industry in the context of economic applications in hospitals. **Keywords:** pharmaceutical industry, medicine, hospital, health sector, organization

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## 1. Introduction

Based on the nature of drug, there are some which have substitute goods, but some do not [1]. As an example for people who need slimming drugs, there are substitute products in the form of fitness equipment to maintain weight [2]. However, many medicines in the hospital do not have substitute goods and are complementary goods for medical treatment. For example, surgery in the surgical room requires narcotic drugs. In this case there is no substitute for narcotic drugs. An action to maintain electrolyte balance require infusion fluid. The absence of substitute goods makes medicines as goods which must be purchased by patients who want to recover from a disease or need certain actions [3]. There are often cases

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of the absence of substitute drugs or alternative actions. As a result, certain drugs that are life-saving are very expensive because there is no other option [4].

As an illustration, Gamimune<sup>®</sup>, a drug containing immuno-globulin for patients who are in critical condition because they have low resistance, has a very expensive price: 25cc for around IDR 1,250,000.00 in 2001. The need in the treatment process is not only 25cc, it may be up to many times. Another example, the drugs for AIDS are very expensive, so it makes unaffordable for people with low economic abilities. It is natural that the patient's family complains because of the high cost of drugs in the hospital which must require humanity value [5].

In this case, there is an impression that the pharmaceutical industry is taking opportunities when people are experiencing adversity and have no other choice because there is no cheaper substitute drug [6]. Health workers who are in ICU or OK often experience the situation when faced with the choice of having to buy expensive drugs, the patient's family is forced to sell family assets, owe, or most drastically is to stop the healing process because of the lack of resources to buy medicine or finance the healing process in the hospital [7].

With these properties, medicine is a strategic economic item in hospitals [8]. Various hospitals report that the profit from the drug sold is the easiest thing to do compared to the advantages in other services, such as laboratory services, radiology, inpatient services, or nutrition services. Although it is difficult to prove, doctors receive various benefits and facilities from the pharmaceutical industry [9]. Meanwhile, people often complain about the high price of drugs needed precisely when people are sick and unable to work [10].

Not all drugs have such properties. In relation to the impact on society, there are drugs which have a large positive externality, such as drugs to cure patients affected by infectious diseases or for immunization [11]. For drugs which have externalities, some countries have policies to make them free medicines financed by the government for people in need [12].

# 2. The Nature of Maximizing Profits in the Pharmaceutical Industry

In principle, the pharmaceutical industry in the world is a sector that runs like other industries. In this nature, it must be understood that the pharmaceutical industry runs with the properties of maximizing profits, from factories, distributors to pharmacy retailers [13]. It is noteworthy that the profit performance of the pharmaceutical industry is very large, greater than the industry average, although it is still lower than the software industry [14]. The drug cases of Viagra® the very expensive drugs show a pattern of maximizing profits. This pattern

is taken because until now there is still little substitute for Viagra®. In this case the demand for Viagra® is inelastic and there is an element of monopoly due to patents [15].

The pharmaceutical industry has a large market value. Two pharmaceutical industry giants, Merck and Pfizer (maker of Viagra®) were ranked 10<sup>th</sup> largest in the world, and the 7 other were in the top 50 in 1999. In Indonesia, according to the Warta Ekonomi report, Kalbe Farma group's total income was ranked 14th in the income of Indonesian conglomerates in 1996.

The competition in the pharmaceutical industry sector is very high, especially for medicines that are no longer protected by patents [16]. In addition to maximizing profit, some other interesting things to note. Drug factories in the world turned out to have different price fixes between countries. It depends on the ability to pay, the demands of the government being a big buyer of drugs, the elasticity of prices, and the state of the health insurance system.

The behavior of the pharmaceutical industry in seeking profit was apparently unaffected by the economic crisis [17]. An overview of the turnover and profit of PT. Kimia Farma Indonesia. The company's profit did not fall despite Indonesia's economic crisis and the increase in profits was quite striking. It is interesting to note that net profit actually increased significantly during the economic crisis. Normative logic states that when the poor are suffering, companies must not be able to gain much from the pain of people. This value-filled statement was not found in the real world.

## 3. Why is the Pharmaceutical Industry Different from Other Industries?

By nature, the pharmaceutical industry is no different from various industries which rely on high technology inventions [18]. The working pattern for producing drugs in the pharmaceutical industry can be divided into two periods. The first period is basic research and development in the laboratory as well as the community. The second period is after the launch of the drug in the community [19]. The first period is an investment that has a high risk of scientific failure. Meanwhile, the second period also has risks in sales. Interestingly in the second period, patent law protects the pharmaceutical industry from competitors (see Figure 1) When the patent period is completed, then other drug manufacturers may produce generic drugs so that revenues will decrease.

This mechanism creates opportunities for the pharmaceutical industry to make a lot of profit. After finding a new drug and having a patent, pharmaceutical companies can make the maximum rate for new products. The rate can be determined as high as possible without worrying about competition. As a result is an extraordinary profit can be obtained. The pharmaceutical industry is one of the most profitable industries. The pharmaceutical industry's profits are ranked 4th after the software, petroleum and food industries. Compared to the industry average, pharmaceutical companies' profits were 13.27% compared to an average of 10.19%.



Figure 1. Two periods of development and sale of new drugs

This profit mechanism is influenced by various typical properties of the pharmaceutical industry that are not found in other industries. One such trait is the existence of Barriers to Entry which will affect the price of the drug. Barriers to entry into the pharmaceutical industry are carried out in various forms: (1) drug regulation; (2) patents; and (3) distribution systems.

The first barrier to entry in the pharmaceutical industry is the regulatory aspect in the pharmaceutical industry which is very strict. In the United States the main regulator is the Food and Drug Administration (FDA), while in Indonesia it is held by the Food and Drug Administration (BPOM). The process of drug testing in the United States (including in a period 1) lasts a long time, can occur up to 15 years with a very complex process. After discovering a new chemical formula to treat a disease, drug companies must conduct trials on animals to find out the short-term toxic power and drug safety. Furthermore, the FDA will give approval to conduct clinical trials arranged in three stages. Phase I begins with a small group of healthy people and focuses on dosage and drug safety. Phase II will be given to a greater number of people (up to hundreds) who have the disease for drug efficacy. Phase III will be performed to thousands of patients with different backgrounds to test their efficacy and safety in more detail. It can be seen that how difficult and expensive this process is.

The second inhibitory factor is the patent granted by the government to the pharmaceutical industry which has succeeded in discovering a new drug. The warmest example is the patent for the drug Viagra®, which is very profitable because the large number of buyer and the high price. With the patent policy, new pharmaceutical companies must have new drugs that require high research costs or produce generic drugs which have no longer patents at the risk of many competitors [20]. After a drug has expired its patent time, other companies can manufacture similar drugs. Therefore, barriers to entry become lower, and prices may fall. These drugs are called generics whose therapeutic impact is the same as branded drugs. Logically, patents are intended in an effort to stimulate scientific research to find new drugs. Diagrammatically, Reuter Business Insight describes the life-cycle of drug production in Figure 2.



Figure 2. Pharmaceutical product life cycle

In life cycle, it can be seen that when the pharmaceutical industry enjoyed a monopoly period, there was only a drug factory which had the right to sell and manufacture drugs because of patents. Patents are valid for 17 years, even up to 25 years. With monopoly patents, there is freedom for factories to set the highest possible price to get the highest profit.

The third barrier to entry is the pharmaceutical industry's highly complex distribution and marketing network system [21]. Distribution and marketing system network has an interesting characteristic that is using the concept of 'detailling', namely pharmaceutical companies through a network of distributors doing a face-to-face approach with doctors who practice in hospitals or private practices. This detailing activity involves many parties and has various nuances including communication to get a mutually beneficial situation between doctors and the pharmaceutical industry [22]. In this communication open the possibility of collusion between doctors and the pharmaceutical industry. With this form of marketing, it will be difficult for new players to enter the pharmaceutical industry.

In society, the system of drug promotion and marketing will increase the high price of drugs. These things are complexly related, so it is difficult to reduce the price of the drug. For example, the policy of shortening patent time, or licensing drug factories in developing countries producing drugs cheaply is strongly opposed by drug companies. The logic used is that if this policy works, the motivation to conduct new drug research will be low. With this logic it is predicted that in the world there will be no new research on the drug, except those sponsored by the government without any optimal patents.

This pattern of drug development makes the pharmaceutical industry does not develop many new drugs for diseases suffered by the poor. The 1,223 new chemical compositions for drugs produced from 1973 - 1996, only 13 were intended for tropical diseases. There was very low investment for the development of TBC drugs which many poor people need. It seems that drug companies do not dare to bear the risk for the development of new drugs in low commercial value.

The interesting question is, is with the presence of generic drugs, then branded drugs will be cheaper and less prescribed by doctors? Generic drug policies were not able to significantly reduce the cost of the drug. Even though there are cheap generic drugs, drug manufacturers still raise prices. In this case, there is a doctor's loyalty to non-generic drug brands. Only 29% of prescriptions were written with generic drugs in the United States. This situation can be understood because of the theory of doctors as patient agents in selecting drugs and information [23]. In agency theory, doctors do not benefit economically from drug price savings. Meanwhile, based on the information, the doctors do not receive enough information about the effectiveness and price of generic drugs. As expected, doctors who are in the managed care system are more likely to write generic drugs. This is due to the pressure of managed care systems with a list of formulary and incentive systems or disincentives for doctors in prescribing drugs.

The pharmaceutical industry's relationship with hospitals and doctors are common around the world. The pharmaceutical industry has even influenced educational hospitals, medical faculties, and researchers. The influence of the pharmaceutical industry on hospitals and doctors is carried out with sophisticated marketing approaches such as using the concept of face-to-face detailing and various other things including sponsoring scientific meetings, journals, and even scientific researches.

It was also reported that pharmaceutical company marketing personnel sent gifts to medical students and residents at educational hospitals. In 2000 pharmaceutical companies spent \$8 billion to please doctors by hiring 83,000 marketing personnel in the United States. In addition, pharmaceutical companies gave \$8 billion for sample drugs in the doctor's practice room. In Indonesia, there is no data like this. However, observations can be seen that the life of doctors and the hospital sector are influenced by the pharmaceutical industry with providing a variety of pleasant things. All these activities are certainly included in the drug pricing process.

Although no detailed data is found, in Indonesia the phenomenon of close relationships between the pharmaceutical industry and doctors and hospitals has a similar picture. In expert association meetings, scientific seminars, hospital management meetings, and various clinical research are funded by pharmaceutical companies. The big question is, is the doctor's behavior influenced by the pharmaceutical industry? Although there are various observations, including an investigative report by Tempo magazine, there has not been any serious research on the relationship between doctors and the pharmaceutical industry in Indonesia.

## 4. Is There Ethics in the Pharmaceutical Business?

Practically the price of the drug is difficult to reduce. In Indonesia the situation becomes more difficult because the government does not have the authority to control drug prices. It is stated that in contrast to the Government of Italy or Canada which regulates the price of drugs circulating in the country, or India which regulates the price of drugs that are considered very essential, Indonesia does not directly regulate the price of branded drugs. Indonesia only makes generic drug programs whose prices are set by the government.

In this situation what can be done? The first approach is to reduce the price of drugs ranging from the research phase to marketing. This emphasis can use a variety of forms, including research financing by the government or the public. In addition, it is expected that cooperation between drug companies that have good production and distribution systems with the government to provide cheap drugs especially for the poor. This approach is being taken by the TB Alliance, a group that is working to develop new TB drugs with mixed funds from various sources, governments, communities, and the pharmaceutical industry. In

addition, there were attempts to shorten the patent time, but this was strongly opposed by the drug industry.

The second approach is to use an ethical approach. In this case there must be normative values in the form of ethics that the health sector has in controlling drug costs. These values will be present if there is awareness about the limited resources for drug procurement, humanity to help sick and miserable people, the right of patients to get the best, mutual trust, and awareness about the selection of drugs as a joint decision. The normative expectations expressed for the health sector and the pharmaceutical industry. Many parties are skeptical of this normative approach, without a firm rule. Important question: is there ethics in the pharmaceutical industry?

An example of corporate business ethics stemming from activities carried out by Merck, a giant drug company. In 1979, Dr. William Campbell, a researcher working at Merck and Co,found evidence that one animal drug Ivermectin® may be able to kill parasites that cause river blindness disease in Africa and Latin America. Dr. Campbell and his team then contacted Dr. P. Roy Vagelos, Chairman of Merck regarding this. This discovery makes the debate within Merck, whether to continue this research and try it on humans. Opposing managers declared that the poor would not be able to afford this drug. In addition, the question of how will it cost its distribution to reach these poor inland? In addition, Merck risks a huge loss because it could destroy the animal drug market of Invermectin® which has a turnover of \$300 million a year, if this human version fails.

In this debate, moral issues arise stating that the benefits of this drug for humans cannot be ignored. This consideration ultimately defeated the profit-and-loss aspect. Based on the research team's proposal, Merck finally agreed to develop it. After 7 years of hard work, at considerable cost the drug can be produced. However, no country wants to buy, not even who. Whereas this drug has the potential to treat 85 million people. What was imagined in the initial debate took place, there was production without any buyers. Finally, Merck decided to give the drug for free to potential sufferers, even providing assistance in its distribution. Merck then collaborated with WHO, forming an international working group to distribute the drug to sufferers safely and to ensure that it would not be sold as an animal drug. In 1996, the drug successfully healed many people as a result of collaboration between Merck and various countries and volunteer agencies.

The important question is why would Merck take risks and then finance things which certainly reduce its profits? In this case Dr. Vagelos stated that the first time his company suspected that one of the drugs for animals can treat humans then the only ethics is to develop it. However, it is further said that the world will remember Merck in this case, so Merck's name will be a good memory. Surely in this case there will be a positive influence for Merck sales in the future.

The example of this case shows that there is still a business ethic owned by Merck, a leading pharmaceutical company with tremendous profits. Indeed, in the short term, it seems that ethics will collide with business purposes to generate maximum profit. However, in the long run ethics and profit will run together. With this case, there is actually a business ethic in a profit-seeking company.

# 5. Conclusion

In conclusion, it can be briefly stated that the pharmaceutical industry was the same industry as other industries with the aim of maximizing profits. This characteristic also occured in the hospital equipment industry which used high technology. The purpose of the hospital sector industry had an indicator of the advantages or ups and downs of the stock price of the industry. Thus, the behavior of the pharmaceutical industry from factories to detailmen was to maximize profits. Important questions were: (1) Will doctors and hospital managers in the non-profit or social hospital system behave for-profit as well, such as the pharmaceutical industry?; (2) Do hospital managers and doctors use medicine as a tool to get the highest income and profit?; and (3) Are there still moral considerations and ethical principles in the pharmaceutical sector in hospitals?

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