Legal Policy to Handle Medicine Price in Indonesia: A Comparison Study With Other Countries

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Abstract The use of medicinal right with an affordable price becomes a necessity for the public. The affordable medicine will reduce public health risks due to the public inability to buying common generic medication. An irrational difference in the medicine selling price at the consumer level was caused by a free price determined by pharmacy industries in the market mechanism. The medicine selling price policies for pharmacies were only accommodated through the Minister of Health Decree Number 720/Menkes/SKIX/2006 which in fact can not provide a solution. Therefore, the government has to control the selling price in the market mechanism and to seek the strong legal force.

1 INTRODUCTION

Today legislation plays an important role in public life because government policies formulate and organize community life. One of the human life aspects that is also formulated in the legislation is health field (Murniati, 2007).

The mandate of the Health Act number 36 of 2009 Article 98, paragraph 1 authorizes the government to control the price of medicine included in the essential one. Medicine is the most important component for public health services and need to be listed, reviewed and refined by government every two years (Undang-undang Republik Indonesia nomor 36 tahun 2009 tentang Kesehatan, 2009).

The proper use of drugs at affordable prices is needed by society. Affordability of medicine will reduce the risk of patients' health due to the inability to buy medicines .Generic medicine with a populist price is one of the main components to seek affordability of medicine (Bina Kefarmasian dan Alat Kesehatan, 2015). The selling price of medicine in Indonesia that is not regulated by goverment cause the irrationally medicine price. Therefore, it will be disadvantaged for patients and at the end will affect public health status.

2 METHODS

This research is normative research by identifying the different types of regulations, application and relevance of rules and laws in the realm of health law approach, especially in legal policy to handle medicine price in several countries related to the problem and identification of juridical facts as an initial effort towards the improvement in handling situations of the medicine price in Indonesia.

3 RESULT AND DISCUSSION

3.1 Medicine Price Control in Different Countries

Until nowadays there has been no definitive answers, opinions are the most correct in terms of medicine prices policy (pricing policy) applied in different countries : government of a country should intervene to regulate and control market mechanism, either directly or through health insurance mechanisms or health financing (Maimunah, 2013) Basically, the regulation and the control of medicine prices in the country can be done with two approaches. First, the approach to the needs (demand) that the emphasis is on the volume or quantity of medicine needs. Second, the availability approach that emphasis is on price.

Medicine policy implemented by the government (regulatory frameworks) of a country can be an intervention based on the medicine needs, the medicine price, or a combination of both. Group of EU countries tend to emphasize the regulation and

control on the availability of medicine. Australia tends to emphasize the volume side. Price controls can be carried from upstream (manufacture price), the price of the distributor, retail price (drugstore) and the price at a hospital.

On Figure 1 shows how to control the medicine prices in some aspects. The regulation and the control of prices basically be done in terms of price, but can also be done in terms of volume (availability). The object of interventions are interrelated elements in the process of health care and medicine, ranging from hospitals and doctors , the pharmacy and the pharmacist and the patient as a consumer (demand sites) and pharmaceutical companies, distributors and retailers (site supply). The end result is the process of the setting and controlling drug expenditures (CAPEX). Empirical facts show the regulation and the control of the medicine prices conducted in various countries will not work optimally with intervening only one element (e.g., reference pricing in the determination of the highest retail price). All elements must intervene simultaneously and parallel.

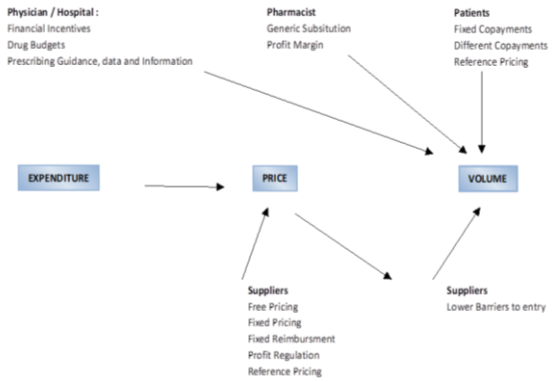

Fig 1. Regulatory framework for Pharmaceutical Market

From a report issued by the US Department of Commerce International Trade Administration, 2004, which outlined policy-setting medicine prices in the OECD (Organization for Economic Cooperation and Development) was found that although the model of setting medicine prices differ from one country to another, but the end result remains the same: the pharmaceutical companies still cannot set the price of their products through the mechanism of market-based price. The most widely used methods in governments of OECD countries in policy setting and the control of the medicine prices are reference pricing, volume limitation, profit control.

3.2 Reference pricing

Reference pricing is a method of setting the price at a set price for the therapy of medication group that is the same as the Reference price. Furthermore, the reference price becomes a benchmark in setting reimbursemen medicine costs and the selling price of medicine produced by pharmacy companies.

3.3 “International” reference pricing

Almost the same as the Reference pricing, methods of "International" Reference pricing are a pricing reference for medicine circulating in a country based on the "basket of price" of medicine from other countries. Generally, some countries have the identical standard (peer countries). For example, in Indonesia, the Reference price is set based on the price of medicine circulating in the Philippines, Malaysia, Thailand and the other countries.

3.4 “Therapeutic” class reference pricing

This method is used to determine the price of the medicine for certain therapy classes and made it as a Reference price. In this way, if the pharmaceutical companies want to produce medicines and to determine of reimbursement insurance program, they should obey the government regulation of Reference pricing. This method is easier for doctors and hospitals in the selection of medicine used by patients without affected the price difference.

3.5 Volume limitation

Several governments on OECD countries impose restrictions on the volume of new drugs sold by the pharmaceutical companies. Goverment and pharmaceutical companies made an agreement called "Price-Volume" pharmaceutical Agreement. Companies only allowed to sell new medicine are produced within certain limits agreed with volume. If the pharmaceutical companies exceed the deal, the pharmaceutical company must provide compensation in the form of price reductions, or excess products on the market should be taken. France and Australia Volume Limitations apply this method in regulating and controlling the price of new medicine in circulation.

3.6 Medicine prices comparison in Indonesia market mechanism

The market mechanism does not seem efficient in controlling medicines prices. The increasing numbers of the medicine manufacturers are not accompanied by a competitive medicine prices. There are very wide price variations in branded generics medicine markets.

Table 1: Price variations in branded generics medicines market

Medicine items	Price per tablet (IDR)			
	GMB *	Company's branded generic medicine		
		X	Y	Z
Mefenamic Acid 500 mg tablet	217	550	1.025	1.475
Metformin 500 mg tablet	231	113	760	975
Metil prednisolon 4 mg tablet	685	1.400	1.745	2.825

**GMB = Generic Medicine Bearing*

From examples on table.1 demonstrate that medicine branded generic prices have variation of 0.5 times to 7 times the premises of generic medicine prices. Very wide price variations which are most likely to cause inefficiency health care. Patients as consumer do not have freedom of choice of medicine, especially medicine that is elected to the ethical authority of physicians as prescribers .

The differences in price between the tablets of 500 mg generic Mefenamic Acid with the logo versions (commonly referred to as generic only) and branded generic versions are only on price and packaging. If the efficacy is said to be different, when the brand is more effective than its generic type means that the generic quality is sub-standard and it should have been prohibited to circulate. The significan difference of price reflects irrationality.

To improve the affordability of medicines for people in obtaining cheaper medicine, the government issued a policy to reduce medicine prices and made rules on the selling price of generic medicine in pharmacies through a decree of the Minister of Health Number 720 / Menkes / SK IX / 2006 on Generic Medicine Prices.

But in fact, it still meets the variation in the price of the medicine. Those condition caused by the differences in the calculation of the percentage of profits taken by the pharmacy so that there is a difference in the selling price of each medicine dispensaries. This caused by the purchase price of medicines in distributor is also cheaper in addition to the price reduction of these medicines that do not affect significantly the pharmacy benefit. In addition, the price of medicines that lowered cost under the highest retail price has to be increased and the price of medicines that higher than the highest retail price has to be decreased.

The wide difference in the generic medicine's selling price at the consumer level was caused by the pharmacy industry freely determining the prices in the market mechanism. Thus, the medicine prices at the retail level as in pharmacies will be influenced by the amount of margin or other operational costs were taken by the provider pharmacy.

In addition, price variations can be caused by: first, component forming medicine prices every pharmaceutical company has a price - forming components of different medicine. In principle, there are some components that can form medicine prices are a) Direct costs , direct costs associated with the production process , including costs, raw materials and additives , the cost of production and distribution costs , b) the indirect costs are costs incurred to support the production process i.e. the cost to profit (marginal cost), administrative costs such as registration and promotion costs , c) packaging, highly branded medicine take seriously in their aesthathic packing appearance , first because the packaging is the largest element in the marketing strategy of a product although it will add to the cost the differences. Production cost may give rise to similar price difference up to 20 times.

Second, the distributor, other factors that lead to high medicine prices is medicine distribution. The existence of a distributor in a region participated in insufficient availability of medicine. Its presence also will affect the selling price of the medicine if the provider difficulty in obtaining medicine from distributors. This is usually caused most of the distributors are outside the city which resulted in the booking of medicines requires a long time and additional costs, such as ordering by telephone or facsimile. For pharmacies, this course will be added to the cost of medicines procurement expenditure so. it increases the selling price of the medicine.

Third, the method of procurement and margins, medicine procurement can be done by buying in bulk or in small quantities. It is highly dependent on the availability of pharmacies funds. The medication methods can also affect the price of the medicine. If the purchase of drugs is done in large numbers, there may be conditioned by the distributor discount, so the price of the medicine can be reduced lower. The amount of margin that could have been taken pharmacies consideration the basic price of medicine is already low, thus, the distributor should increase the margin to obtain higher profits. In this case, the providers often pay less attention to business ethics. Good business is a business that upholds the values like considerations of right and wrong, good-bad, fair-unfair, honest-dishonest and so on. For generic medicine, the government has set the highest benchmark selling price in which it will limit the

highest margin. Even so, there are the selling prices of generic medicines over the limit price set by the government (Departemen Kesehatan RI, 2006).

Based on Sulistiowati, The difference in price occurs because of the competition at the pharmacy level. However, the medicine is a commodity that is a requirement for all layers of society in which the state should be responsible for regulating the price so that they won't be disadvantage for the parties. It is appropriate with the constitutional mandate that has spirit towards the welfare state

3.7 Legal Policy in Indonesia

An affordable price is one thing which is important to ensure access to essential medicines in the public sector and the private sector. Affordability is a component of the national medicine policy required political support and legislative namely to reduce import taxes of essential medicines, the policy of generic medicines and generic medicine substitution and price equation.

Pricing policies implementation as a key strategy in national medicine policies require a good information status from pharmacies stakeholders, a total public medicine expenditure and the total production sold values in the country that could determine specific achievements on the the pricing policy implementation (Sjabana, 2004).

It also requires a good system capacity, particularly pharmaceutical pricing policy structural component itself. The varied generic medicine selling prices shows a lack of government's role as regulator, particularly in terms of health technical problems responsibily. In the end, the regional autonomy era should increase the government roles , especially in order to improve the health services efficiency.

There are several ways that can be taken to increase the government roles, including by education, managerial, and regulatory approaches. The way education can be reached with the provision of information and communication through the mass media, brochures, and further formal education. The second way is by means of managerial, by implementing the National Essential Drugs List, procurement and distribution, financial formulary rules and how regulation can be done with supervision, promotion, audit prescriptions and pharmacy services (Purwaningsih and Sri Suryawati, 2003).

Policies regarding the price of generic medicine must still refer to the legal provisions in Indonesia through the Law of the Republic of Indonesia Number 36/2009 on Health Article 98:

> "Pharmaceutical preparations and medical devices must be safe, efficacious / useful, quality, and affordable"

Based on that article, policies regarding the generic medicine prices it should be safe, efficacious and has an affordable price. So that, the public can be convinced to use generic medicine as well as having the certainty price that could be covered by the whole society. In addition, the Law of the Republic of Indonesia Number 36/2009 on Health Article 98, 3rd paragraph:

> "Provisions on procurement, storage, processing, promotion, distribution of pharmaceutical and medical devices must meet the standards of quality pharmacy services are set by Government Regulation"

The generic medicine circulation should be established through government regulation. However, until nowaday there have been no government regulations that regulate it so that there are no legal norms that regulate the translation in the form of he Law/36 of 2009 on Health implementation, in particular regarding generic medicine circulation setting in the community. The Role of the government is also regulated in the Law of the Republic of Indonesia Number 36/ 2009 on Health Article 98 4th paragraphthat states:

> "The government is obliged to foster, organize, control and supervise the procurement, storage, promotion, and distribution as referred to in paragraph (3)"

It became the government duties to play monitoring function roles related to generic medicine prices as well as it circulation in the community as of the benefits of generic medicine (Kotler, 2009). Law No. 8 of 1999 on Consumer Protection has outlined what became the consumer rights related to drugs , included the right to recieve the correct, clearly and transparantly information, the right for security and safety guarantee, the right regarding compensation, right to choose and to be heard, and the right to advocacy, rights which are governed by legislation. The existence of the irrational difference in medicine price makes the patient suffer. If the generic medicine manufacturers and the government recognize this reality, they should issue policy of generic medicine price more seriously (Embrey and Health, 2012).

We conclude in setting the generic medicine pirce the government can use the method "Therapeutic" Class Reference Pricing. This method has been used to determine the medicine price for certain therapy classes and made it as a reference

price. In that way, if the pharmaceutical companies want to produce medicines and to determine of reimbursement insurance program, they should obey the government's reference pricing regulation. This method is easier for doctors and hospitals in the selecting the medicine used by patients without affected on price difference. This method can also handle the high price medicine circulation in the community because the government already has a strong oversight function on controlling the generic medicines prices.

4 CONCLUSION

An irrational difference in the medicine selling price at the consumer level was caused by unlimited prices determination by pharmacy in the market mechanism. Price variations can be caused by: forming components, the medicines price, the distributor, the goods procurement and margins methods as well as the medicine supply and demand mechanism. To improve the affordability of medicines for people in obtaining a cheaper medicine price, the government issue policies to reduce medicine prices and make the rules on the generic medicines selling price in pharmacies industries through Health Ministerial Decree Number 720 / Menkes / SK IX / 2006 on Generic Drug Prices. But, in fact, it still can be seen an irrational variation in medicine price at the consumer level. The government role become the key to improve supervision function and uphold the law enforcement against violations in irrational generic medicine sales. The government should also review the material contained in the Decree of the Minister of Health Number 720 / Menkes / SK IX / 2006 on Generic Medicine Prices where should the materials contained in a government regulation that is binding.

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