The Role of Medicine Pricing Policy for Improving the Affordability of Medicines

(Peranan Kebijakan Obat dalam Memperbaiki Keterjangkauan Obat)

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Abstract: Imperfect market characteristics was occurred on medicines and affects to the medicine price. It is important to regulate medicine prices. The objective of this review was to describe various medicine pricing policy interventions. Published articles regarding medicine price policies were collected and reviewed. The review results showed that medicine prices can be regulated in the medicine supply chain by the industry, importers, distributors and health facilities such as pharmacies, hospitals and medicine sellers. Developed and high income countries generally regulate the prices of medicines and are part of a health insurance system. Medicine pricing regulation in developing countries and Lower Middle Income Countries (LMIC) is not well established. The regulation of mark-ups in distribution channels is the most common strategy used by LMIC. Small country with only a few pharmaceutical facilities has a weak bargaining position. The application of cost-plus pricing is quite effective in a small country. In developing countries with a large market segment and adequate pharmaceutical industry facilities the price competition method is an effective strategy option to get lower prices. In conclusion, the application of medicine pricing policy is dynamic. The medicine pricing system can be changed or combined with other methods, depending on the evaluation of the policy implementation.

Key words: Medicine, price, policy.


Kata kunci: Obat, harga, kebijakan.
INTRODUCTION

MEDICINE is a pharmaceutical product that has imperfect market characteristics. Consumers or patients cannot directly determine their treatment options, since treatment was determined by the physician. In addition, the patient often does not obtain complete information regarding their treatment options and price. Because of these characteristics, medicine prices could be more expensive than they should be. This affects affordability to the community, and therefore it is necessary for the government to regulate medicine prices\(^{(1)}\). Medicine prices have become an important topic in health care, because price affects the accessibility to medicine. Not only in developing countries, but also in developed countries such as the US, medicine price has become a critical discussion in parliament\(^{(2)}\). Therefore, many studies focus on medicine price as a research topic with an overview of various perspectives.

The main objective of the paper is to describes of medicine pricing policy intervention on the price, order to improve access to affordable medicines.

MATERIAL AND METHOD

Published articles regarding medicine price policies were collected and reviewed to describe the type of policy that implemented in other countries.

RESULTS AND DISCUSSION

**Medicine Pricing Policy.** Medicine pricing policy is a regulation to control medicine price to be better access to medicines\(^{(3)}\). Determining a “fair” price could be achieved by regulating medicine prices, but this is the most difficult part of the development of a medicine pricing policy. Medicine prices can be regulated in the medicine supply chain by the industry, importers, distributors and health facilities such as pharmacies, hospitals and medicine sellers. In practice, the government may use a combination of regulations in each chain. For example, the government sets the price at the pharmaceutical industry level and the maximum mark-up that can be taken by wholesalers or health care facilities\(^{(1,4)}\).

**Price Regulation in the Production Stage.** Price setting in this stage is conducted in the pharmaceutical industry or at the importer level. According to Rietveld and Haaijer-Ruskamp (2002), at this level there are five methods for setting medicine prices\(^{(5)}\), as follows:

**a. Cost-plus**

Pricing is set by calculating the cost of production, cost of raw materials, R&D and margin for each product. Policymakers negotiate with the pharmaceutical industry to establish the margin for each product. This method complicates obtaining production cost information. The pharmaceutical industry is often not transparent and can manipulate the information provided\(^{(6)}\). India has implemented a cost-plus pricing method for essential medicines whereby it cannot exceed twice the cost of their production\(^{(7)}\).

**b. Profit ceilings/Profit-based pricing**

Here, the government sets a maximum return on capital (ROC) and return on sales (ROS) to the pharmaceutical industry that sells their products to the government. The system implemented in the UK is termed the Pharmaceutical Price Regulation Scheme (PPRS)\(^{(8)}\). ROC or ROS are set individually by the pharmaceutical industry and reviewed every year. In 2009, the ROC was set at 21% and ROS at 6%\(^{(9)}\).

According to Mossialos (2006), the PPRS is an unique in its implementation, as the buyer’s power is very large. In this case, there is a unique relationship between the government and pharmaceutical industry, since the disclosure of information by the pharmaceutical industry might not be applied universally. Similar to the cost-plus pricing method, there is also the disadvantage of the manipulation of information by the pharmaceutical industry\(^{(10)}\).

**c. Price comparison**

Pricing is set by comparing medicine prices within a country or with other countries\(^{(11)}\). Internal/national reference pricing sets the price of one medicine for a group of medicines with the same therapeutic classes or that have the same function in a single country. Reference prices can be based on the average price or lowest price in the group. This method is commonly used to establish the reimbursement price of a medicine\(^{(8,10)}\). The pharmaceutical industry can set the price according to what they want, while the government or insurance provider only pays the reference price and the consumer must pay the difference\(^{(11)}\). The implementation of national reference pricing in Norway, Germany, Sweden, South Africa and Canada has reduced the price of medicines\(^{(12-15)}\). New Zealand has also implemented internal reference pricing\(^{(16)}\).

Price setting by comparing the prices of the same medicine in other countries is called international/external reference pricing. In 2010, external reference pricing was widely used in 23 countries in Europe, except Denmark, Germany, Sweden and the UK. Reference baskets (other countries used for comparison) were used by the state in fewer than 10 countries from the same economic level. In general, EU countries use the average price of the reference country. Most
countries in Europe make external reference pricing the primary criteria for price setting, except in Belgium and Italy where it is used as supporting information\(^{(17,18)}\). In 2012, the UK additionally performed an international price comparison in setting the ceiling profit of the PPRS\(^{(17)}\). Many studies show the reference price to be an effective method of reducing the price of generic medicines, but the reference pricing system is ineffective for medicines that are still under patent\(^{(19)}\).

**d. Price negotiation**

Price setting is carried out by negotiating medicine prices between the buyer (e.g., hospitals, health insurance or government) and the industry. It is usually implemented on the purchase of large volume or value. Therefore, buyers have a great bargaining position. Negotiations can be carried out centrally or at a local level\(^{(4)}\). This strategy has been used in Austria, France, Spain and Sweden\(^{(20)}\).

**e. Pharmacoeconomic evaluation**

Price setting is carried out by evaluating the cost-effectiveness of a medicine. In general, pharmacoeconomic evaluation is used to determine the price of medicines in the insurance system that requires more consideration of the value for money. In principle, pharmacoeconomic evaluation can calculate the value of the benefits gained by the new medicine compared with established medicine\(^{(21)}\). The value then would be appraised for cost-effectiveness, usually by the use of a threshold (public willingness to pay for a gained in health benefit)\(^{(22)}\). The value would increase with lower price or improved benefit. As such, the evaluation is commonly used to bargain for lower price in order to justify its value for reimbursement.

This method is applied in Australia and the Ontario province in Canada\(^{(23)}\). EU countries such as Finland, the Netherlands\(^{(24)}\), Sweden\(^{(25)}\) and the UK (National Institute for Health and Clinical Excellence/NICE) had conducted economic evaluations to determine the medicines that provide “value of money”. In addition to the UK and Canada, this system has also been implemented in France, Germany, Italy, Spain and Switzerland. There is a variation in the application of EU economic evaluation; this system is generally used for setting medicine prices for reimbursement. Furthermore, Finland, France, Norway and Sweden use economic evaluation guidelines for negotiations\(^{(26)}\). In Asia, South Korea is the first Asian Countries which is implemented the economic evaluation to determine the price for reimbursement\(^{(27)}\).

**Regulation of Medicine Prices at the Distribution Level.** Rietveld and Haaijer-Ruskamp (2002) classify price settings at the distribution level\(^{(40)}\):

1. **Setting the price at the wholesaler or distributor level.** Regulation is implemented by limiting the distribution margin distributor or wholesaler. In addition to applying the external or internal price comparison system, 21 of the 27 countries in Europe also regulate wholesaler mark-ups\(^{(28)}\). Other countries that regulate wholesaler mark-ups are Ecuador, Honduras, Panama and Paraguay\(^{(29)}\).

2. **Price setting at the pharmacy level**

Price setting in pharmacies can be carried out from two perspectives: medicine/product-oriented and patient/services-oriented. There are three methods for setting prices based on the orientation of the product. First, in the Fixed Margin (Cost + fixed percentage) method, the amount of mark-up is fixed, e.g., the maximum mark-up that could be taken is 25%. Second, in the Mark-up Negotiation, the mark-up is set by negotiation between the distributor and buyer (e.g., health insurance, government or hospital). Third, the mark-up may be Digressive/Cost + declining percentage, where the mark-up is determined based on the proportion of the price. If the medicine price were high, then the mark-up allowed would be low, and vice versa.

Medicine prices based on services (patient-oriented) are set by co-payment and fixed fees per prescription. Co-payment methods are applicable in South Korea and are used to reduce medicine expenditure per patient and the per-unit price of medicines\(^{(30)}\). The application of co-payment in Medicare Beneficiaries lowers the expenditure of medicines to 14% due to the increased use of generic medicines\(^{(31)}\). In addition to conducting pharmacoeconomic evaluations when pharmaceutical companies propose their medicines, the Pharmaceutical Benefits Scheme in Australia also regulates the price of medicines to patients using a co-payment system. The patient must pay the difference in price if he or she wants a medicine that exceeds the cost of the co-payment\(^{(32)}\).

In Ireland, the pharmacist receives a fixed fee per prescription for patient services to members of general medical services and drug payment schemes. There are differences in determining the price of the medicine under both schemes. Under general medical services, medicine prices are in accordance with the prices set by the government and pharmacists cannot apply a profit mark-up. Under drug payment schemes, pharmacies can add a 50% mark-up from the medicine prices set by the government. For patients not under any schemes, medicine pricing is fully depends to the pharmacy\(^{(33)}\).

**Impact of the Implementation of Medicine Pricing Policies in the Pharmaceutical Industry.** Medicine prices can be reduced by implementing a medicine pricing policy. However, such a policy may also provide unintended impacts. Along with
a decrease in medicine prices, the profit of the pharmaceutical industry will reduce\(^{(30)}\), which can decrease a company’s spending on innovation research\(^{(35,36)}\).

The impact of medicine pricing policy is influenced by the size of the regulated market and the length of the policy applied. If the medicine pricing policy was applied to the previously non-regulated countries, then it would generate a big impact of revenue reduction on the pharmaceutical industry. In addition, the longer the policy is applied, the more the pharmaceutical industry’s revenues will decrease. The decline in revenue to 16.8% occurred with the application of medicine pricing policies with direct price control methods, while the method of budget control and economic evaluation made about 6% lower revenue.

The impact of reduction in revenues was not significant on the application of medicine pricing policies using profit controls and reference pricing\(^{(34)}\). For example, over a 19-year period (1986-2004) there was a decline in R&D spending in both countries that regulated medicine prices as in the EU and in countries that applied the free pricing system, such as the United States. However, the decline in R&D spending was greater in countries that implemented the regulation of medicine prices. In 1986, R&D spending in the EU was more than in the United States by 24%, while in 2004, R&D spending in the United States was 15% higher than in the EU countries\(^{(36)}\). In New Zealand, the application of reference pricing can affect the patient’s clinical outcomes. The determination of simvastatin as a medicine reference has failed to achieve success in the outcome therapy. In patients previously using fluvastatin who then switched to simvastatin, an increase in total cholesterol, LDL cholesterol and triglyceride levels occurred\(^{(37)}\).

Research on the Price of Medicines. Before 1990, studies of medicine prices were very limited and the methods used were diverse, making it difficult to compare the results of studies\(^{(38)}\). In 1999, Health Action International (HAI) began conducting research on medicine prices in developing countries and in OECD nations and showed that the prices of LPG medicines in developing countries are more expensive than those in OECD countries\(^{(39)}\). After researching the price of medicines in 1999, in 2001 the WHO and HAI started developing a standard method for measuring the price, availability and affordability of medicines. A pilot test was conducted in nine countries in 2001–2002. The first edition of the manual was launched in 2003\(^{(40)}\).

Currently, the manual used is the second edition launched by WHO and HAI in 2008. The second edition manual contains methods for determining price components and additional guidelines for making policy choices. Guidelines for the survey include facility, sector and medicine type. In addition, standardised data collection forms and worksheets are available for data analysis. All aspects are described in detail\(^{(41)}\). Until 2011, these methods were used for 53 surveys in 43 countries\(^{(42)}\). Systematic and standardised methods allow us to determine the position of medicine prices in one country compared with others. The price of medicines is influenced by many factors, such as delivery of medicines, types of facilities that establish the medicine, route of distribution and patent status\(^{(43)}\). Medicine prices are grouped into two categories: patient retail price and procurement price.

a. Patient Retail Prices

Patient retail price is the price that must be paid by the patient to receive the medicine. The findings consistently show that the patient retail price in the private sector is higher than that in the public sector\(^{(42,44-47)}\). However, some countries show the opposite result; in Vietnam, the patient retail price (either LPG or IB) in the public sector is more expensive than that in the private sector\(^{(48)}\). Further, in Tajikistan and three provinces in China (Hubey, Shandong and Shanghai), the prices of LPG medicine in the public sector are more expensive than those in the private sector\(^{(49-52)}\).

Variations in prices are also influenced by the types of medicines. Generally, the price of IB medicine is more expensive than that of LPG. A survey in Malaysia showed that in the private sector and other sectors, IB medicine prices are more expensive than LPG medicines. In addition, IB and LPG medicine prices are higher than the IRP\(^{(46)}\). In the private sector in Thailand, IB medicine prices in the private sector are almost three times more expensive than LPG prices. All maximum retail prices (MRPs) of LPG and IB medicines are higher than the IRP. Consistent with other survey findings, the prices of median price ratio (MPR) medicines in the private sector are higher than those in the public sector. However, an interesting finding in Thailand is that the price difference of patients with procurement prices in the public sector is greater than the private sector, 32% and 19.96% respectively. Meanings that the public sector benefits more than the private sector\(^{(47)}\). A comparison of medicine prices in ASIAN countries is shown in Table 1.

Among high income countries, medicine prices in the US are expensive compared with Japan, Europe (Sweden, Germany, Denmark, Italy, Switzerland, France and Spain), Canada, New Zealand and Singapore. Among European countries, Switzerland has the most expensive medicine prices. Medicine
prices in Japan are higher than those in European countries\(^{56}\).

In 2009, HAI performed a snapshot survey on the price of ciprofloxacin in 66 countries. The cheapest ciprofloxacin LPG prices were found in Myanmar, Sri Lanka, Laos, Zimbabwe and Vietnam. The most expensive LPG medicine was in Switzerland, Austria and Australia. The price of IB ciprofloxacin medicine in Indonesia was ranked 44\(^{th}\) of the 66 countries. The price of IB ciprofloxacin in Indonesia are the most expensive in Southeast Asia, while the LPG price of ciprofloxacin was ranked sixth cheapest of the 91 countries surveyed\(^{57}\). In 2010, HAI conducted a second snapshot survey to measure insulin prices. The most expensive prices were found in Austria, the US, Costa Rica, Congo, Palestine and Indonesia\(^{57}\). However, this snapshot did not provide an overview of the overall medicine price within a country.

b. Public Sector Procurement Prices

In addition to patient retail price, the WHO and HAI methodology determines public sector procurement prices. The efficiency of public sector medicine procurement was reached when the value of the MPRs ≤ 1\(^{45}\). India and China have a public sector procurement price that was lower than the IRP\(^{49, 58}\).

The results of a recent study in India showed the same results, namely Delhi Assembly Government procurement prices (0.61) and the Central government (0.53)\(^{59}\). In Indonesia, the medicine procurement price in the public sector is 1.74 times higher than the IRP\(^{53}\). Efficient public procurement is also carried out by UNRWA to Palestinians. Here, the MPR procurement prices are equal to or less than the procurement prices of international NGOs such as MSH, JPD and IDA\(^{60}\). Inefficient public sector procurement prices were shown in Indonesia, Tajikistan, Philippines Vietnam, and Thailand\(^{47, 48, 52-54}\).

c. Previous Medicine Pricing Studies In Indonesia

There are few studies of medicine prices and availability in Indonesia. In 2003, Firni and Suryawati conducted research on generic medicine prices in Bengkulu. The study was performed in one province and the facilities studied were pharmacies. The findings of this study showed that the selling price of LPG medicine to the patient was 2.12 times more expensive than that for the IRP. Branded generic medicine prices were more expensive than LPG prices by 1.45–7.97 times\(^{61}\).

In 2004, the availability and affordability of medicines have been examined by WHO and HAI in many countries including Indonesia, which carried out the survey in collaboration with the National Institute of Health Research and Development\(^{53}\). The survey was conducted in six provinces representing four regions in Indonesia: South Sumatra, Jakarta, East Java, South Sulawesi, South Kalimantan and Papua. Similar to the findings in other countries, the availability of LPG medicines in the public sector is lower than that in the private sector (47% vs. 62%, respectively). The private sector often provides IB medicines (26%) compared with the government sector (6.7%). There are no differences in the availability of LPG medicines between provinces.

LPG medicine prices in both the public and private sectors are higher than the IRP. The median MPR of LPG medicines in the public sector is 2.54 times the IRP and 2.78 in the private sector. IB medicine prices are very expensive, 22–23 times higher than the IRP. Some medicines are almost 100 times higher than the IRP. The MPR public sector procurement price is 1.74. This shows that public sector procurement is inefficient\(^{53}\).

The weakness of this study is that the medicines surveyed do not fully represent those used in Indonesia. This survey also used the first edition of the WHO and HAI methods. Forty medicines should have been surveyed: 26 medicines from the HAI and WHO core list and 16 supplementary medicines. Incompatibility in the medicine of choice is likely to occur in the core list of medicines that are not widely used in Indonesia. Medicine selection methods for the survey were revised for the second edition of the

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<th>Country</th>
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<th>IB</th>
<th>Private</th>
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<td>2.54</td>
<td>21.8</td>
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<td>Malaysia (46)</td>
<td>1.09</td>
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<td>6.77</td>
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<td>Thailand (47)</td>
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<td>4.36</td>
<td>3.3</td>
<td>11.6</td>
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<td>Vietnam (48)</td>
<td>11.41</td>
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<td>8.3</td>
<td>44.61</td>
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<td>Shandong, China (51)</td>
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<td>0.77</td>
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<tr>
<td>Hubei, China (49)</td>
<td>1.04</td>
<td>11.25</td>
<td>0.68</td>
<td>19.94</td>
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<td>Shanghai, China (50)</td>
<td>2.03</td>
<td>5.64</td>
<td>1.77</td>
<td>8.76</td>
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<tr>
<td>Shaanxi (55)</td>
<td>0.97</td>
<td>1.53</td>
<td>8.36</td>
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<td>Tajikistan (52)</td>
<td>2.28</td>
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survey manual(41).

In 2006, NIHHRD conducted a medicine price survey in four provinces in Indonesia. However, this study did not use the WHO and HAI methodology(62). Because medicine prices are not compared with the IRP, the patient retail price and public procurement price were compared with maximum retail price of MoH (MRP of MoH) in 2005. Surveyed facilities include health centres, hospitals, pharmacies, medical offices and distributors. The study showed that the majority of patient retail prices exceed the price set by the government. In general, the public sector procurement price in all provinces concurred with the MoH procurement price. However, this research did not compare the price position in Indonesia with international prices.

Another finding of this study was the great variation in prices between LPG and branded generic medicines. There were no differences in price and availability between provinces. Interestingly, the region with low government finance did not have low medicine availability. Further, there was no price difference between regions(62).

Another study was conducted in Kendari in 2007 survey manual(41).

Table 2. Comparison of the findings of medicine price studies in Indonesia.

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<td>Six provinces</td>
<td>Four Provinces</td>
<td>One province</td>
<td>Four Provinces</td>
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<td>Province name</td>
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<td>Sumatera Selatan,</td>
<td>Jakarta, Pekan</td>
<td>Kendari</td>
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<td>MPR of LPGs vs. IRP</td>
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<td>MPR of most sales vs. IRP</td>
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<td>MPR of IBs vs. IRP</td>
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<td>2.53 (private sector)</td>
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<td>14.53 (private sector)</td>
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<td>Affordability to hypertension treatment (generic)</td>
<td>2.12</td>
<td>6.74 (private sector)</td>
<td>2.0 (private sector)</td>
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<tr>
<td>Affordability to hypertension treatment (IB)</td>
<td>2.2 days’ wages (atenolol LPG)</td>
<td>22.78 (private sector)</td>
<td>32.15 (private sector)</td>
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<td>Variation in the price of branded generic compared with LPG</td>
<td>1.45 - 7.97</td>
<td>9 days wages (atenolol IB)</td>
<td>2.2 days’ wages (atenolol LPG)</td>
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<td>Ratio MRP of MoH with IRP</td>
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<td>Ratio patient retail price with MRP of MoH</td>
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that evaluated the MoH-MRP and IRP. In addition, it also compared the patient retail price with the MoH-MRP. It found that the MPR of LPG medicine is similar to the IRP. However, the patient retail price in pharmacies was much more expensive than the MoH-MRP (5.4 times higher for LPGs)\(^{(65)}\).

Unfortunately, both studies in Bengkulu and Kendari did not represent national conditions, as the survey was carried out in one province and with one type of facility. Moreover, these studies did not look into the availability. The study of Siahaan (2006) did not use the WHO and HAI survey. The study of Siahaan (2004) was considered comprehensive research and provides an overview of the availability, price and affordability of medicines in Indonesia. A summary of research into medicine prices in Indonesia is shown in Table 2.

Developed and high income countries generally regulate the prices of medicines and are part of a health insurance system. Most high-income countries have implemented a combination of regulation systems for regulating medicine prices\(^{(18)}\). The United State is a rare example of a developed country that has implemented a free pricing system; medicine prices in the United State are expensive under this system\(^{(36, 65)}\). A medicine prices policy is generally applied in the developed countries and the methods used are varied\(^{(66)}\).

Direct price control was the most commonly used method in the years 1992-2004. In general, the developed countries use this system, such as Denmark, which applied medicine prices in a cut/freeze system for six years (1994-2000), but since 2001 it has switched to international price comparisons. The Netherlands has used EPR since 1996. In addition to the United Kingdom, the use of budget control systems to regulate medicine prices is also applied in Spain, Hungary, France and Italy. Profit control is rarely used by OECD countries to regulate medicine prices. Spain applied this system in 1995 before using a budget control system and IRP.

The success of a profit control system as implemented in the UK is unknown. In fact, medicine prices in the UK are higher than in most other EU countries. The application of profit control systems in other countries is questionable because it is a monopsony purchaser and inefficient. The application of rate-of-return provision requires investment in the big pharmaceutical industry so as to affect the government’s budget and ultimately the public welfare\(^{(19)}\).

The application of a reference pricing system is only effective when there is a competitive market. However, if the mechanisms are not transparent or there is collusion, the reference pricing will not work\(^{(11, 19)}\). External reference pricing is an established method and the most widely used by countries in the EU. This method has proven to be effective in getting rational medicine prices\(^{(17)}\). Reference pricing succeeded in lowering the price of medicines but had no significant impact on medicine spending. Furthermore, in Spain, the implementation of reference pricing did not increase the market share of generic medicines. Another weakness of the reference pricing system is the possible increase in medicine prices which were previously cheaper than the reference price\(^{(67)}\).

A tender system can lower medicine prices in the short term, but in the long term could affect the government income. The decline margin of pharmaceutical company can lead to reduce the pharmaceutical investment. Furthermore, income tax will be reduced. In addition, the impact of the tender system for ambulatory care is not yet clear\(^{(18)}\). A free pricing system causes the price of originator medicines whose patent has expired to remain high compared with the generic medicines\(^{(18)}\).

There was a lot of evidence showing that the application of pharmacoeconomic evaluations played an important role in directing health insurers to negotiate prices and choose medicines which is giving more benefit to the patient. However, to apply pharmacoeconomic evaluation in the health-care system, the issue of willingness to pay needs to be considered to get a reasonable price\(^{(68)}\).

In contrast with the situation in developed countries, medicine pricing regulation in developing countries and LMIC is not well established. The regulation of mark-ups in distribution channels is the most common strategy used by LMIC. However, evidence on the regulation of medicine prices in LMIC is limited\(^{(65, 69)}\). In a small country with only a few pharmaceutical facilities, the country has a weak bargaining position, therefore generally the government cannot set prices. The application of cost-plus pricing is quite effective if it is implemented in a country that has few pharmaceutical industry facilities. In developing countries with a large market segment and adequate pharmaceutical industry facilities the price competition method is an effective strategy option to get lower prices\(^{(70)}\).

\section*{CONCLUSION}

In practice, the application of a medicine pricing policy is dynamic. The medicine pricing system in a country can be changed or combined with other methods if the evaluation does not provide optimal results or generates unintended impacts.
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