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# MEDICINE PRICING POLICIES: THE IMPACT ON AVAILABILITY AND AFFORDABILITY IN FOUR PROVINCES IN INDONESIA

**By**

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**Thesis submitted in fulfillment**
**of the requirements for the degree of**
**Doctor of Philosophy**

**February 2013**

# *DEDICATION*

*I dedicate my thesis to my beloved family, who always inspire and support me in each step of the journey of life:*

*My parents, Nasrun Syukur & Asniati*

*My husband, Suyatno*

*My children, Putri Shafaa Salsabila & M. Hafizh Rasendriya*

## ACKNOWLEDGEMENTS

First and foremost, I would like to thank and express my sincere gratitude to my main supervisor Professor Mohamed Izham Mohamed Ibrahim, co-supervisors Associate Professor Asrul Akmal Shafie, PhD and Prof. Sri Suryawati for their invaluable guidance and supervision throughout the study. Their support and encouragement made it possible to complete my PhD study. Faculty of Pharmacy Pancasila University and Ministry of Education Republic of Indonesia are acknowledged for providing financial support for my PhD study. I would like to thank Prof. Wahono Sumaryono as a Dean Faculty of Pharmacy Pancasila University and Associate Professor Mohammed Azmi Hassali for their support during the study.

I would like to acknowledge Martuti Budiharto, MM and Selma Siahaan, M.Sc, from NIHRD of MoH, Fatimah Umar, MM, and Sadiah, MPH from Department of Public Medicine of MoH, Nani Sukasediati, M.Sc from WHO Indonesia Country Office, Dr. Siti Zulaiha, Prasidayani Nurita, MPH, and Mr. Masrur Chuldori for helping me to conduct this study.

Margaret Ewen and Martin Auton from Health Action International and Alexandra Cameron from World Health Organization are acknowledged for their valuable guidance and technical support in this study.

I would like to thank the pharmacist directors of the Provincial Health Offices, hospital directors, hospital pharmacist managers, and private pharmacists for their collaborations. I am grateful to the data collectors and data entry personals for their

valuable work in data collection and data entry. I would like to thank all colleagues in the Faculty of Pharmacy Pancasila University for supporting in my PhD Journey.

I would like to acknowledge and dedicated this thesis to my father, my lovely husband Suyatno, my two lovely kids Chaca and Hafizh for your patience, consideration, support and love through the years and made it possible to complete my PhD journey.

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   ***(WHO fellowship)***

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## LIST OF ABBREVIATIONS

| | |
|---|---|
| BPS | Badan Pusat Statistik (Indonesia's Central Statistic Agency) |
| BPJS | Badan Penyelenggara Jaminan Sosial (Social Security Agency ) |
| EMR | Eastern Mediterranean Region |
| CPI | Consumer Price Index |
| GDP | Gross Domestic Product |
| GMP | Good Manufacturing Practice |
| GST | Goods and Services Tax |
| HAI | Health Action International |
| HI | High Income |
| IB | Innovator Brand |
| IDR | Indonesian Rupiah |
| IMF | International Monetary Fund |
| INN | International Non-proprietary Names |
| IRP | International Reference Price |
| LMIC | Low-middle Income Countries |
| LPG | Lowest-Priced Generic |
| MoH | Ministry of Health |
| MSH | Management Sciences for Health |
| MPR | Median Price Ratio |
| MRP | Maximum Retail Price |
| NA | Not Available |
| NDP | National Drug Policy |
| NEML | National Essential Medicines List |
| NIHRD | National Institute Health Research and Development |
| OECD | Organization for Economic Co-operation and Development |
| PBS | Pharmaceutical Benefit Scheme |
| PPP | Purchasing Power Parity |
| PPRS | Pharmaceutical Price Regulation Scheme |
| ROC | Return on Capital |
| ROS | Return on Sales |
| SEAR | South East Asian Region |
| SJSN | National Social Security System |
| UHC | Universal Health Coverage |

| | |
|---|---|
| UK | United Kingdom |
| UNWRA | United Nation Reliefs and Work Agency for Palestine Refugees in the Near East |
| VAT | Value Added Tax |
| VS | Versus |
| WHO | World Health Organization |

**POLISI PENETAPAN HARGA UBAT: IMPAK PADA TAHAP SEDIA ADA DAN KEMAMPUAN MEMBELI UBAT DI EMPAT NEGERI DI INDONESIA**

## ABSTRAK

Kerajaan Indonesia telah memberikan komitmen untuk penyediaan ubat-ubatan dengan harga yang berpatutan. Kerajaan membangun polisi harga runcit maksimum bagi ubat generik dengan nama International *Non-proprietary Name (INN).* Objektif kajian ini adalah untuk menilai impak polisi harga ubat terhadap harga, tahap sedia ada, kemampuan membeli ubat, dan menilai kandungan dan konteks dalam pembangunan polisi harga ubat di Indonesia. Bahagian pertama kajian dilaksanakan dengan menggunakan metodologi yang dibangunkan oleh Pertubuhan Kesihatan Sedunia (WHO& HAI). Harga, tahap sedia dan kemampuan membeli ubat diperoleh dari sektor awam, swasta, dan sektor yang lain di 4 negeri di Indonesia (Sumatera Selatan, Jakarta, Yogyakarta dan Sulawesi Selatan). Jenis ubat yang dipilih adalah ubat generik dengan harga paling rendah (LPGs) dan ubat berjenama (IB). Harga rujukan antarabangsa tahun 2009 (IRP) telah digunakan untuk mengira nisbah harga median (MPR). Bahagian kedua kajian telah dijalankan untuk memperolehi maklumat dan konteks dalam pembangunan polisi harga ubat. Kaedah yang digunakan ialah: penilaian dokumen mengenai dasar-dasar penentuan harga ubat, temu bual mendalam dengan 10 pemberi maklumat utama dan 10 pemerhatian kepada mesyuarat rasmi mengenai harga perubatan. Transkrip dianalisis menggunakan analisis kandungan kualitatif. Kaedah triangulasi digunakan untuk membandingkan data yang diperolehi daripada penilaian dokumen, temu bual secara mendalam dan pemerhatian mesyuarat. Harga beli ubat di sektor awam masih tidak cekap, kerana MPR lebih tinggi berbanding IRP (1.34). Harga beli ubat sektor awam

cekap apabila MPRs $\leq 1$. Di semua sektor, harga ubat berjenama adalah mahal, MPRs 7-133 dibandingkan IRP. Ubat berjenama lebih sering ditemui di sektor swasta dan lain daripada di sektor awam. Perbezaan harga ubat di antara sektor dan negeri adalah tidak signifikan secara statistik. Selepas penetapan polisi, harga ubat LPGs didapati lebih rendah di dibandingkan sebelum penetapan polisi. Ubat LPGs dijual melebihi harga yang ditetapkan oleh kerajaan. Tahap sedia ada di sektor awam serupa dengan sebelum pelaksanaan polisi harga ubat, sementara di sektor swasta tahap sedia ada menurun. Pekerja di sektor awam dengan pendapatan paling rendah lebih mampu membeli ubat generik dibanding ubat berjenama. Kerajaan mengawal selia harga ubat generik tidak berjenama dengan menggunakan kaedah *cost-plus pricing*. Proses pembangunan polisi harga ubat generik telah berpatutan, namun penggunaan hasil kajian mengenai harga ubat, pautan antara institusi kerajaan dan organisasi antarabangsa, dan penggunaan hasil pemantauan belum dioptimumkan. Pilihan polisi harga ubat di Indonesia yang didedahkan oleh kajian ini ialah: membangunkan senarai positif, persaingan harga, perundingan, perbandingan harga dan pengurangan cukai. Strategi yang dicadangkan menggabungkan dengan sistem insurans. Sebagai kesimpulan, polisi harga ubat generik telah berjaya dalam mengurangkan harga LPGs. Tidak ada polisi harga ubat yang dibangun kerajaan untuk mengawal harga ubat berjenama dan berjenama generik. Polisi harga ubat generik tidak menjejaskan tahap sedia ada di sektor awam, tetapi ia mengurangkan tahap sedia ada di sektor swasta. Terdapat keperluan untuk melakukan penambahbaikan terhadap proses pembangunan polisi harga ubat.

**MEDICINE PRICING POLICIES: THE IMPACT ON AVAILABILITY AND AFFORDABILITY IN FOUR PROVINCES IN INDONESIA**


## ABSTRACT

The government of Indonesia has established a commitment to the provision of affordable medicines. The retail price of unbranded generic cannot exceed the maximum retail price set by the Ministry of Health. The generic medicine pricing policy that has been implemented by the Indonesian government must be evaluated. The objectives of this study were to evaluate the impact on the price, availability and affordability of selected medicines and to evaluate the context, process, evidence and links of generic medicine pricing policies development in Indonesia. The first part of the study was conducted using a standardized methodology developed by the World Health Organization and Health Action International. The prices, availability and affordability of 50 medicines were measured at public, private and NGO facilities in four provinces in Indonesia (Sumatera Selatan, Jakarta, Yogyakarta and Sulawesi Selatan). The type of medicines selected were Lowest Price Generics (LPGs) and Innovator Brands (IBs). The 2009 International Reference Price (IRP) was used to calculate the median price ratio (MPR). The second part of the study was conducted using the following methods: a review of medicine pricing policies documents, in-depth interviews with 10 key informants and 10 observations of meetings about medicine prices. Transcripts were generated and analyzed using qualitative content analysis. Triangulation was applied to the comparative information obtained from document reviews, in-depth interviews, and meeting observations. The results showed that the public sector procurement price was still inefficient (MPRs=1.36). Public sector procurement price is efficient if the MPR $\leq$ 1. The prices of IBs were

found to be very expensive, the MPRs around 7-133 times than IRP. The IBs were found more often in private and NGO hospitals than in the public sector. A small variation in LPGs prices and availability were found among sectors and provinces. The prices of LPGs medicine lowered after the implementation of the medicine pricing policy. However, the LPGs was sold above the maximum price of MoH. The availability of LPGs in the public sector had been similar in terms of availability before the medicine pricing policies were implemented, while in the private sector it had decreased. The LPGs are generally more affordable for the lowest paid government workers than for the IBs. The Indonesian government regulated the price of unbranded generic medicines by using a cost-plus pricing method. The development process of medicine pricing policy was well established. However, links among government institutions in the monitoring activities has not been optimized. The use of evidence was limited. The medicine pricing policy options revealed in this study include the development of a national positive list, price competition, negotiation, price comparisons and tax reduction. The proposed strategies have been incorporated within the insurance system. In conclusion, generic medicine pricing policies have succeeded in lowering the price of LPGs in all sectors, but many outlets still sell LPGs at a price which is above the maximum price. The generic medicine pricing policy does not affect availability in the public sector, but it decreases availability in the private sector. There is a lack of a policy to regulate the high price of branded generic medicine and IBs. Therefore, there is a considerable need to improve medicine pricing policy in Indonesia.

# CHAPTER ONE

# GENERAL INTRODUCTION

## 1.1 BACKGROUND

Medicine plays an important role in the health care system. In developing countries, medicines account for approximately 20–60% of health expenditures (WHO, 2004a). Medicine is one of the factors that cause inefficiency in the health care service. Owing to the rising cost of health care in developing countries, it is crucial to keep health care services available and affordable by the community (WHO, 2010a). Most people in developing countries use out-of-pocket payments to purchase medicines, making them unaffordable and inaccessible.

Public access to medicines should be a concern for both governments and private health providers. The accessibility of medicine can be affected by price and availability. People cannot access medicine due to low availability and high price (Donald *et al.*, 2011). Governments should play a major role in developing medicine policies to ensure their availability and affordability (WHO, 2004b).

Industry pricing policies, government pricing policies, national health policies, excessive patent extensions or the monopoly of the production of certain medicines all affect the price of medicines (Olcay and Laing, 2005). To reduce the price of medicines, regulation can be implemented at different stages of the supply chain such as wholesale prices, retail prices, drug taxes and reimbursement prices (Aaserud *et al.*, 2006). In many countries, regulations regarding medicine pricing policy have been implemented.

In addition to price, availability is another important factor towards ensuring access to medicines. Low availability in the public sector has often occurred in low income and Low/Middle Income Countries (LMIC). For example, very low availability has been observed in Yemen. Moreover, regional availability is also low in Africa (29.4%) compared with 54.4% in the US (Cameron *et al.*, 2009). Mean availability in the public sector is lower than that in the private sector in all regions in the world (Cameron *et al.*, 2011).

In the public sector, the low availability of medicines can affect affordability. Some public sectors provide free or low priced medicines. However, when medicines are unavailable in the public sector, patients are forced to buy them in the private sector where medicine prices may be more expensive (Cameron *et al.*, 2011). Economies are divided according to 2012 GNI per capita,. The groups are: low income, $1,035 or less; lower middle income, $1,036 - $4,085; upper middle income, $4,086 - $12,615; and high income,$12,616 or more (World Bank, 2012). According to this classification, Indonesia is classified as a lower middle-income country and developing countries (United Nations, 2012). Therefore Indonesia is also facing similar problems on the medicines. To describe the medicine price problems in Indonesia, it is important to understand the Indonesian health care system and its pharmaceutical system.

### 1.1.1 Indonesian Health Care System

Decentralisation in the health care system has been implemented since 2001. Under this system, districts and municipalities have more authority and responsibility for government services and financial planning. Budget control and health planning have

also moved from the central level directly to the district or municipality (WHO, 2010b).

The central government has the responsibility of maintaining health care services in terms of developing and setting national standards, national indicators, national goals and national training modules for health care professionals, advocating for continued health financing and increasing the access of the poor to public health services (Holloway, 2011). The organizational structure of Indonesian health care system in the decentralization is shown in Figure 1.1.

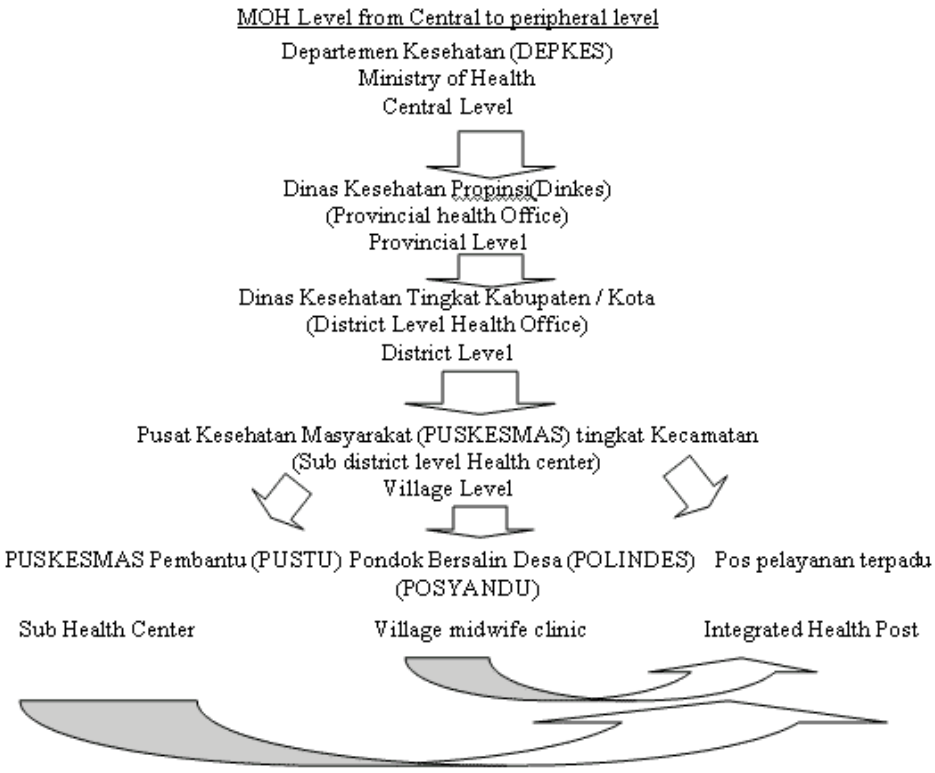


Figure 1.1 Organizational structure of Indonesian health care system. Adapted from Country Health System Profile, WHO, 2010.

### 1.1.1.(a) Indonesian health insurance

The government of Indonesia is establishing universal health coverage (UHC) for all Indonesian citizens under Law number 40/2004. The law has been issued but the implementation of it will be carried out in 2014. To date, the coverage of government social insurance (ASKES, JAMKESMAS and JAMKESDA) is about 40% and 2% by private insurance (Holloway, 2011). ASKES is a health insurance that covers civil servants and their families. Private employers and workers are covered by JAMSOSTEK. Both ASKES and JAMSOSTEK deduct the salary of the employee to pay the premium. JAMKESMAS is health insurance for the poor, with the premium paid by the government.

By 2014, it is expected that all Indonesian citizens will be covered by health insurance under the Indonesian UHC. The government is developing a system for UHC implementation, including a pharmaceutical system. ASKES was appointed as the implementing agency of the Social Security Providers (namely Badan Penyelenggara Jaminan Sosial) for the health sector, which was mandated by the 2004 National Social Security System (SJSN) Law.

### 1.1.1.(b) Mortality and morbidity in Indonesia

The blood circulation system is the main cause of morbidity and acute respiratory infection for mortality. Table 1.1 shows the top 10 diseases that cause mortality and mortality in Indonesia (MoH, 2010a).

**Table 1.1 Top 10 diseases that cause mortality and morbidity**

| Disease | Mortality | Morbidity |
|---|---|---|
| Disease 1 | Blood circulation system | Acute upper respiratory tract infection |
| Disease 2 | Infections and parasitic disease | Unspecified fever |
| Disease 3 | Specific conditions initiated in perinatal states | Skin and subcutaneous diseases |
| Disease 4 | Respiratory disease | Diarrhoea and gastroenteritis |
| Disease 5 | Gastrointestinal disease | Refraction and accommodation (eye disorder) |
| Disease 6 | Trauma, poisoning and other external causes | Dyspepsia |
| Disease 7 | Endocrine, nutritional and metabolic disease | Primary essential hypertension |
| Disease 8 | Urinary tract system | Pulp and periapical disease |
| Disease 9 | Neoplasm | Ear and mastoid processus disease |
| Disease 10 | Other (unspecific signs, symptoms or laboratory results | Conjunctivitis and other conjunctival disorder |

### 1.1.2 Indonesian Pharmaceutical System

The pharmaceutical system in Indonesia plays a role in the public and private sectors. The Ministry of Health is responsible for ensuring the medicine supply in the public sector. Since decentralisation in 2000, drug supply in the public sector has been managed by local district governments. The district health office procures the medicines from distributors by tender. Medicines are then distributed to all primary health care facilities, such as primary health care centres (PUSKESMAS), sub-primary care centres (PUSTUS), maternal child health clinics (POLINDES), community clinics (POSYANDUS) and mobile clinics (PUSKESLING) (Holloway, 2011). Patients receive medicines from these facilities free of charge.

Besides district health offices, district public hospitals also play an important role in the supply of public medicines. A difference mechanism is used by public hospitals to procure their medicines. Public hospitals procure medicines directly from wholesalers or distributors. In public hospitals, patients still have to pay for their

medicines if they are not covered by insurance. For the patient who is covered by the JAMKESMAS, ASKES and JAMSOSTEK insurance, public hospital services only for the secondary care. The patients have to go to primary health center or family general practioner for the primary care. The supply chain structure in the public sector is shown in Figure 1.2.

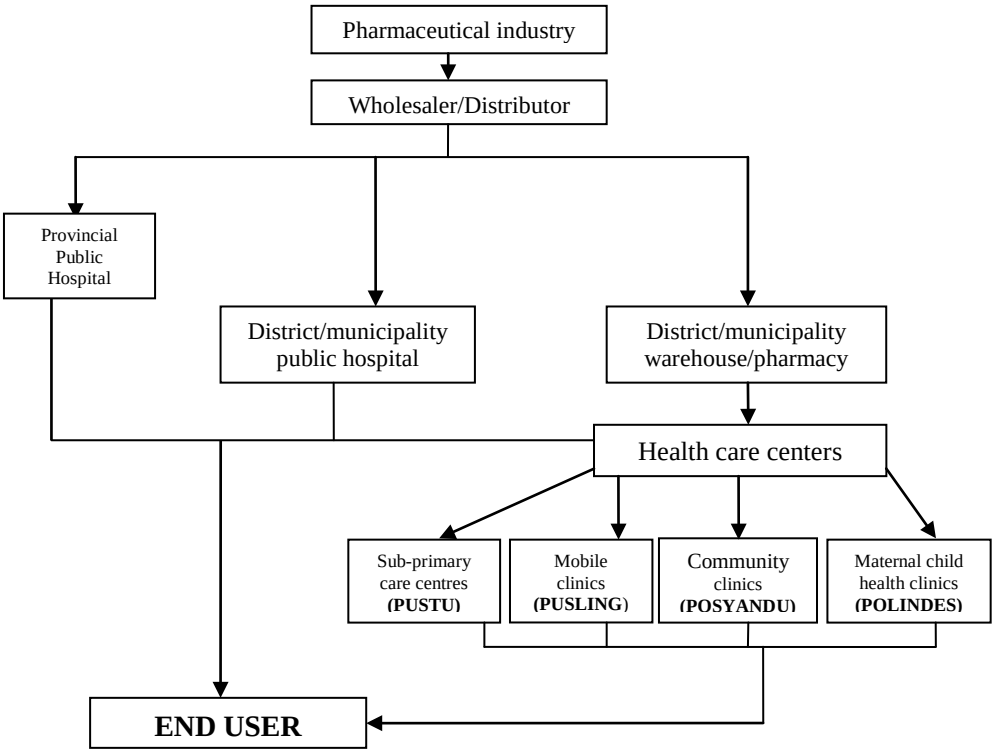


Figure 1.2 Structure of the public sector pharmaceutical supply in Indonesia

In the private sector, the medicine supply chain begins in the pharmaceutical industry. In 2011, there were 202 pharmaceutical industries (Indonesian Drug Regulatory Agency, 2011). Four industries are state-owned enterprises and eight are domestic industries that produce generic medicines. Domestic industries dominate the market for branded generic medicines.

Originator brands and new medicines are produced by multinational industries. Pharmaceutical industries should produce their medicines in Indonesia, under Decree

1010, only companies registered as 'licensing pharmaceutical companies' will be allowed to obtain marketing approval (MoH, 2008a). Imported medicines are allowed only for special cases and programs and need the approval of the MoH and Drug Regulatory Agency.

Pharmaceutical industries sell their medicines to distributors. About 2600 distributors sell these medicines to pharmacies, hospitals and licensed drug stores. Patients can receive medicines from pharmacies, hospitals or licensed drug stores through out-of-pocket expenses or by being covered by private insurance. The supply chain in the private sector is shown in Figure 1.3 (Wang *et al.*, 2009).

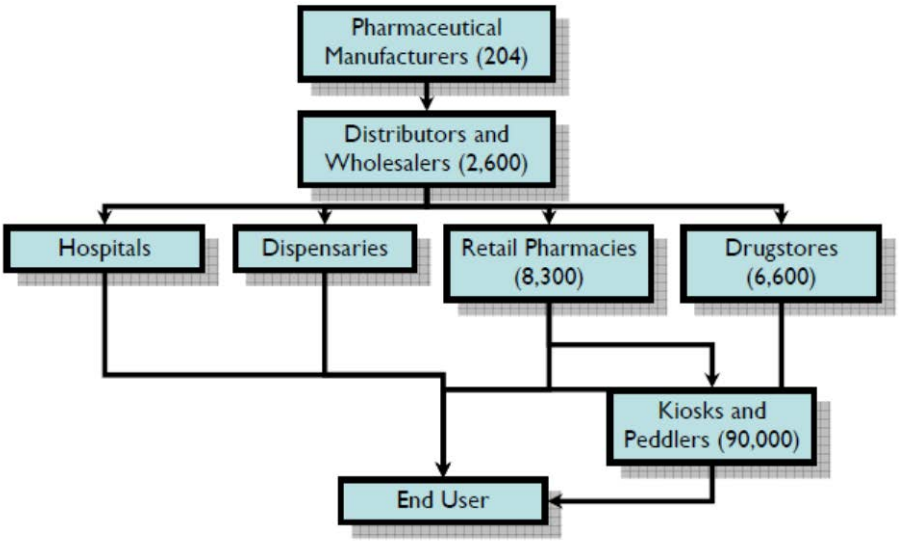


Figure 1.3 Structure of the private sector pharmaceutical supply in Indonesia. Adapted from: *Private Sector Health in Indonesia: A Desk Review* by Wang *et al*, 2009, Bethesda, MD: Health Systems

Data in Indonesia show that GDP per capita in 2010 was US$ 2980.843 (IMF, 2010). Per capita spending on medicines is slightly over US$ 12 annually. Compared with GDP per capita, spending on medicines in Indonesia is low (Wang *et al.*, 2009). The pharmaceutical market in Indonesia in 2010 was valued at around US$ 3.787 billion.

The public sector market (health centres and public health programs) has a share of around 10–12%, while the public hospital market share is around 12-15% (World Bank, 2008). The data described for the public sector market share are lower than that in the private sector.

In Indonesia, most people purchase medicines through out-of-pocket payments, around 60% to 85%. (Wang *et al.*, 2009). In choosing a medicine, Indonesian consumers are influenced by brand name medicines, although cheaper generic medicines are available (World Bank, 2008). In fact, survey results in LMIC and low income countries show the percentage difference in price between originator brands and low priced generics (LPGs) in the private sector to be above 300% (Cameron *et al.*, 2009). This situation, in turn, can lead patients to pay higher prices for the same medicines and same degree of effectiveness.

Besides the mark-ups on the price of medicines, high prices could also be caused by taxes and mark-ups (WHO and HAI, 2008). In Indonesia, value added tax (VAT) is applied to medicines. Taxes on medicines should be a part of government concern in the development of medicine pricing policy.

The government of Indonesia has given a political commitment to improve society's ability to access medicines by implementing the National Drug Policy. This is broadly aimed at assuring the sustainable and fair distribution and affordability of medicines to achieve the highest standards of public health. The component of the Indonesian National Drug Policy are: financing, availability and acces, equitable distribution, affordability, the selection of national essential medicines, rational

medicine use, quality assurance on safety and efficacy of the medicine, research and development, human resources development and monitoring and evaluation (MoH, 2006a).

This commitment is also shown through the development and implementation of several medicine pricing policies. The government sets a maximum retail margin for unbranded generic medicines. However, most policies issued by the government only regulate the price of generic medicines with an International Non-proprietary Name (INN). In addition, the Indonesian pharmaceutical market is dominated by branded generics (generic medicines with company brands). The market share of unbranded generic medicines ranges from 10% to 15% of the total medicines market in Indonesia. Originator, patent and branded generic medicine prices are not regulated by the government.

The pricing mechanism of branded generic and originator brand medicines are mainly left to market forces (see Figure 1.4). Therefore, the price of innovator or branded generic medicines in Indonesia could be three to 100 times more expensive than generic medicines (Siahaan *et al.*, 2004). Based on this condition, there is a need for an appropriate medicine pricing policy or pricing mechanism that can cover the public and private sectors in Indonesia.

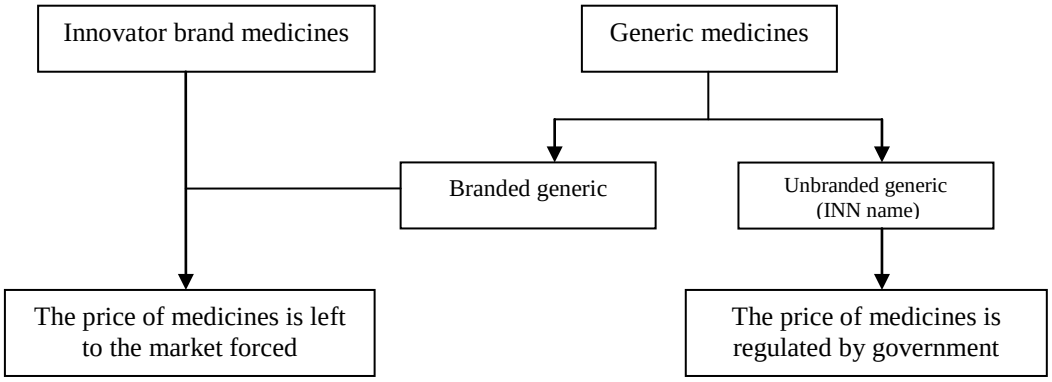


Figure 1.4 Schematic diagram medicine pricing policy mechanisms in Indonesia

## 1.2 PROBLEM STATEMENT

The price of medicines is one of the obstacles to accessing medicines in Indonesia. Several studies in Indonesia show the price of medicines to be high (Siahaan *et al.*, 2004; Siahaan, 2006; Restuani and Anggriani, 2009).

The availability of medicines in Indonesia is often low, especially for unbranded generic medicines (Siahaan *et al.*, 2004). Generic medicines with brand names and off-patent medicines (originator medicines) can often be better known than unbranded generic medicines. Furthermore, the prices of brand name and originator medicines are higher than unbranded generic medicines. Thus, the affordability of medicines is a problem in the Indonesian health care system. People in Indonesia often pay for expensive medicines. In fact, the per capita income of Indonesia's population is still in the group of Middle Income Countries, with a per capita GDP of U$ 2980.43 in 2010 (IMF, 2010). In addition, recent data from the Indonesia's Central Statistics Agency stated that 12.36% of the population are classified as poor condition. Indonesian government's official poverty line of 233,740 rupiah per capita

per month, which is less than $28 dollars (BPS, 2012). If unbranded generic medicine availability is low, people have to buy medicines at more expensive prices; as a result, the poor would find it difficult to buy the medicine, and even for middle-income residents, providing expensive medicine for long-term treatment, such as for chronic diseases, may lead to poverty (Niens et al., 2010).

The high price of medicine and low availability are also an issue for healthcare services. Healthcare services that are mainly owned by the government have limited funds to run the health service. If medicines are not available at low prices, then healthcare facilities should provide more funds for the branded generic medicine or originator medicine. This situation results in inefficiencies in the medicine management by healthcare facilities, such as low availability of medications or the availability of only branded generic and innovator medicine at a more expensive price. Low availability of medicines will affect the quality of health care because the patients cannot gain access to medicines at affordable prices. In the end, this will cause problems of morbidity and mortality.

Another problem in Indonesia, is that there is no evidence on developing medicine pricing policies. The content, context, actors and criteria used in determining the price of medicines in the policy remain unclear.

### 1.3 RATIONALE AND IMPORTANCE OF THE STUDY

Between 2005 and 2011, the government of Indonesia implemented a number of pricing policies in order to set the maximum retail price (MRP) for generic medicines and a procurement price for the public sector. However, rapid changes in medicine

pricing policies often occur in Indonesia. For example, in 2006 the prices in the policy were changed twice. Such frequent changes in price can cause problems during implementation and may result in an ineffective policy. The previous policy was still in the socialisation program or just at the beginning of the implementation stage when another new policy was released. Thus, the impacts of the previous policy are unknown.

Rapid changes can indicate suboptimal policy development. However, the availability of scientific evidence is insufficient to help determine whether medicine prices, availability and affordability have improved after the implementation of these policies. No systematic evaluation has been conducted to assess the effectiveness and impact of these pricing policies.

An appropriate medicine pricing policy should be developed around the following main principles: scientific evidence-based, a fair and transparent process and linkages between the key actors involved in policy development. Moreover, the policy and institutional context are also important factors that should be considered (Start and Hovland, 2004). Furthermore, the development of the medicine pricing policy is an important part of establishing good policy. For example, it is important to involve various parties or stakeholders in the development process (Gilson, 2012). However, little attention has been paid in evaluating whether the policy development process was carried out in accordance with the stages established in the policy guidelines.

The key actors can be identified at national or international levels. At the national level, the key actors can be categorised as (i) persons responsible for policy development including internal government and outside government institutions; (ii) persons responsible for implementing the policy, such as middle managers, health workers, patients and citizens; (iii) and civil society or interest groups who seek to influence the formal policy process (Gilson, 2012). The role of key actors in developing the medicine pricing policy in Indonesia has not been explored.

Based on the above description, the price of medicines in Indonesia remains an important issue for the government, pharmaceutical industry, third party (insurance) providers as well as consumers. Therefore, there is a need to investigate the price of medicines as well as their availability and affordability after medicine pricing policies have been implemented. Moreover, a good policy is necessary to achieve the goal of increasing availability and at affordable price. It is also important to evaluate the mechanism used in developing medicine pricing policies.

## 1.4 OBJECTIVES

### 1.4.1 General Aim

The main aim of the research is to evaluate the impact of government policy intervention on the price, availability and affordability of selected important medicines in order to improve access to affordable medicines for all.

### 1.4.2 Specific Aims

In order to achieve the general aim, the study has the following specific aims:

(i) To compare public sector procurement prices with the prices paid by patients in the public and private sectors.

(ii) To compare retail prices of 50 medicines across different segments of health care sectors and provinces.

(iii) To compare availability of 50 medicines across different segments of health care sectors and provinces.

(iv) To evaluate the affordability of the treatment costs of selected diseases (i.e. Hypertension, Diabetic, Asthma).

(v) To evaluate the impact of government policy intervention on medicine prices and availability.

(vi) To identify strengths, weaknesses, contexts, content and evidence in developing medicine pricing policies.

(vii) To identify policy options for improving medicine pricing policy development and implementation in Indonesia.

## 1.5 CONTRIBUTION OF THE STUDY

The findings of this study describe medicine prices, availability and affordability after the government of Indonesia implemented a series of medicine pricing policies. The findings also provide data on the effectiveness, pricing trends, impacts and mechanism used in developing the implemented policies.

The findings of this study could contribute to the government to develop effective medicine pricing policies and the implementation strategies in Indonesia. Moreover, the government can adopt the survey method used in this study to monitor and evaluate the implementation of the medicine pricing policy regularly.

Information from this research could also be used by health care facilities both in public and private sectors as a basis for negotiating more affordable prices for medicines.

The results of this study may be used as information for the pharmaceutical industry about the situation concerning the price and availability of medicines in Indonesia. Furthermore, the pharmaceutical industry could use the information from this study to prepare their pricing strategies.

The pharmacy profession could further enhance its role in health care by providing information on the alternative choices of similar medicines at different prices. Furthermore, this study is expected to provide benefits to patients, their families and the general public who could have easier access to the required medicines at affordable prices.

Data on availability, price and affordability are required by both local and international NGOs, International agencies and health professionals to map, create programmes and provide advocacy related to increasing people's access to essential medicines at affordable prices.

## 1.6 SYNOPSIS OF THE THESIS

This thesis is divided into five chapters. The following Chapter 2 provides a literature review and a conceptual framework on medicine pricing policy as well as on price, availability and affordability. An overview of policy analysis processes is also presented in this chapter. Chapter 3 presents the methodology and results of the study regarding the impact of the medicine pricing policy on price, availability and

affordability. The compliance of health facilities to medicine pricing policies is also described in this chapter. Chapter 4 describes the results of the qualitative study on the evaluation of the Indonesian medicine pricing policy. This chapter also presents policy options for Indonesia based on the content and context. The thesis concludes in Chapter 5 with a summary of the study. This chapter also proposes a number of recommendations to improve the implementation of the medicine pricing policy in Indonesia. In addition, the limitations of the study are describes in this final chapter.

# CHAPTER TWO

# LITERATURE REVIEW AND

# DEVELOPMENT OF CONCEPTUAL FRAMEWORK

## 2.1 MEDICINE PRICING POLICY

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 (WHO, 1998).

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 (WHO, 1998; Rietveld and Haaijer-Ruskamp, 2002).

### 2.1.1 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.

### 2.1.1.(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 (WHO, 1998). India has implemented a cost-plus pricing method for essential medicines whereby it cannot exceed twice the cost of their production (Kumar, 2004).

### 2.1.1.(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) (Borrell, 1999). 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% (Department of Health UK, 2012).

According to Mossialos (2006), the PPRS is 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 (WHO, 1998).

### 2.1.1.(c) Price comparison

Pricing is set by comparing medicine prices within a country or with other countries (WHO, 1998). 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 (Danzon and Chao, 2000; Huttin, 2002; Schneeweiss, 2007). 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 (Ghislandi, 2011). The implementation of national reference pricing in Norway, Germany, Sweden, South Africa and Canada has reduced the price of medicines (Aronsson *et al.*, 2001; Pavenik, 2002; Rothberg *et al.*, 2004; Brekke *et al.*, 2009). New Zealand has also implemented internal reference pricing (Huttin, 2002; Aaserud *et al.*, 2006).

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 (Dylst and Simoens, 2010; Leopold *et al.*, 2012). In 2012, the UK additionally performed an international price comparison in setting the ceiling profit of the PPRS (Department of Health UK,

2012). 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 (Mossialos *et al.*, 2006).

### 2.1.1.(d) Price negotiation

Pricing is set 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 (Rietveld and Haaijer-Ruskamp, 2002). This strategy has been used in Austria, France, Spain and Sweden (Mrazek, 2002).

### 2.1.1.(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, phamacoeconomic evaluation can calculate the value of the benefits gained by the new medicine compared with established medicine (Drummond *et al.*, 1997). 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) (McGuire *et al.*, 2004). 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 (Bloor *et al.*, 1996). EU countries such as Finland, the Netherlands (Hoomans *et al.*, 2012), Sweden (Lundkvist, 2002) 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 (Graf von der Schulenburg and Hoffmann, 2000). In Asia, South Korea is the first Asian Countries which is implemented the economic evaluation to determine the price for reimbursement (Yang *et al.*, 2008).

### 2.1.2 Regulation of Medicine Prices at the Distribution Level

Rietveld and Haaijer-Ruskamp (2002) classify price settings at the distribution level:

#### 2.1.2.(a) 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 (Vogler *et al.*, 2008). Other countries that regulate wholesaler mark-ups are Ecuador, Honduras, Panama and Paraguay (Sarmiento, 1995).

### 2.1.2.(b) Price setting at the pharmacy level

Price setting in pharmacies can be carried out from two perspectives: (1) 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 (Lee *et al.*, 2012). The application of co-payment in Medicare Beneficiaries lowers the expenditure of medicines to 14% due to the increased use of generic medicines (Gilman and Kautter, 2008). 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 (PBS, 2012).

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 (Purcell, 2004).

### 2.1.3 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 (Sood *et al.*, 2009), which can decrease a company's spending on innovation research (Vogel, 2004; Golec and Vernon, 2006).

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 (Sood *et al.*, 2009). 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 (Golec and Vernon, 2006). 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 the outcome therapy. In patients previously using fluvastatin who then switched to simvastatin, an increase in total cholesterol, LDL cholesterol and triglyceride levels occurred (Thomas *et al.*, 1998).

### 2.1.4 Indonesian Medicine Pricing Policy

Setting medicine prices is also applied in Indonesia by the MoH. Each medicine price regulation is set forth in a decree. Since 2005–2011, the government has issued policies to regulate the prices of unbranded generic medicines. However, evidence that describes the method used to control medicine prices in Indonesia has not yet been demonstrated. Information is usually obtained from interpersonal communication or newspapers. In addition, there are no price regulations for branded generics, innovator brands (IBs) and patented medicines. The prices for all three types of medicines are determined by market mechanisms. The publication of medicine pricing policy studies in Indonesia remains very limited.