

## CHAPTER II

### LITERATURE REVIEW



#### 2.1 Good Pharmacy Practice and Pharmaceutical Care

Good Pharmacy Practice was first adopted by the WHO from The International Pharmaceutical Federation (FIP). The guidelines of good pharmacy practice are based on the pharmaceutical care given by a pharmacist. All practicing pharmacists are obliged to ensure that the service is of an appropriate quality to every patient. Good Pharmacy Practice is a way of clarifying and meeting the obligation (Wiedenmayer et al., 2006; FIP, 1997).

The term *Pharmaceutical Care* is recognized as a philosophy of practice with the patient and the community, as the primary recipient of the pharmacist's actions. The most generally accepted definition of this new approach is: "*Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life*" (Wiedenmayer et al., 2006). While the basic concepts of Pharmaceutical Care and Good Pharmacy Practice are mostly identical, it could be said that Good Pharmacy Practice is the way to implement Pharmaceutical Care.

*Good Pharmacy Practice requirements* (WHO, 1996; FIP, 1997).

- a. Good Pharmacy Practice requires that a pharmacist's first concern must be the welfare of the patients in all settings.

- b. Good Pharmacy Practice requires that the core of the pharmacy activity is the supply of medication and other health care products, of assured quality, appropriate information and advice for the patient, and monitoring the effects of their use.
- c. Good Pharmacy Practice requires that an integral part of the pharmacist's contribution is the promotion of rational and economic prescribing and appropriate medicine use.
- d. Good Pharmacy Practice requires that the objective of each element of pharmacy service is relevant to the individual, is clearly defined and is effectively communicated to all those involved.

*In satisfying these requirements (WHO, 1996; FIP, 1997),*

- Professional factors should be the main philosophy underlying practice, although it is accepted that economic factors are important.
- There must be pharmacist input to decisions on medicine use.
- The ongoing relationship with other health professionals, particularly physicians, should be seen as a therapeutic partnership involving mutual trust and confidence in all matters relating to pharmacotherapeutics.
- The relationship with other pharmacists should be as colleagues, each seeking to improve pharmacy services, rather than as competitors.
- In practice organizations and group practices, the pharmacy manager should accept a share of responsibility for the definition, evaluation and improvement of quality.
- The pharmacist should be aware of the essential medical and pharmaceutical information about each patient. Obtaining such information is simplified if

the patient chooses to use only one pharmacy or if the patient's medication profile is available.

- The pharmacist needs independent, comprehensive, objective and current information about therapeutics and medicines in use.
- Pharmacist in each field of practice should accept personal responsibility for maintenance and assessment of competence throughout their professional working lives.
- Educational programmes for entry to the profession should appropriately address contemporary and foreseeable future changes in the practice of pharmacy.
- It is necessary to specify national standards of good pharmacy practice that should be adhered to by practitioners.

So, there are four main elements of Good Pharmacy Practice to be addressed (WHO, 1996; FIP, 1997):

1. Activities associated with promotion of good health, avoidance of ill health and the achievement of health objectives.
2. Activities associated with the supply and use of medicine and items for the administration of medicines or otherwise related to treatment. These activities may be undertaken in the pharmacy or in an institution or home care setting.
3. Activities associated with self care, including advice about and, where appropriate, the supply of a medicine or other treatment for the symptoms of ailments that can properly be self treated.
4. Activities associated with influencing prescribing and medicine use.

## 2.2 Self Medication

One of the four elements of Good Pharmacy Practice is associated with the information from pharmacist about self-care of the patient. Self-care is what people do for themselves to establish and maintain health, prevent and deal with illness (WHO, 1998). Self-care is a broad concept including hygiene (general and personal); nutrition (type and quality of food eaten); lifestyle (sport activities, leisure, etc.); environmental factors (living condition, social habits, etc.); socioeconomic factors (income level, cultural beliefs, etc.); and self medication (WHO, 1998).

Self-medication is becoming a more popular choice for common ailments as a result of safe, effective medicines available from the pharmacy without the need for a doctor's prescription. Self-care (where patients purchase over the counter medicines) is one of the important components of health care systems (Wiedenmayer et al., 2006). Pharmacists have the expertise to advise both on the choice of medicines and their safe and effective use. The right choice of self-treatment can prevent some conditions from developing or help others clear up more quickly.

Pharmaceutical care is rising in consequence with the challenges of self-care, with greater involvement in self-care for the pharmacist. Pharmacist should deal with greater responsibility towards their customers and an increased need for accountability (WHO, 1998).

The increase in self-care is due to a number of factors. These factors include: socio-economic factors; lifestyle; ready access to drugs; the increased potential to manage certain illnesses through self-care; public health and environmental factors;

greater availability of medicinal products; and demographic and epidemiological factors (WHO, 1998).

### 2.3 Rational Use of Medicine

Most leading causes of death, disease and disability in developing countries can be prevented, treated or at least alleviated with cost effective essential medicines. On the other hand, millions of people are underprivileged regarding access to essential medicines. Many of those who do have access are given the wrong treatment, receive too little or too much medicine for their illness, or do not use the medicine correctly, adding to the problem of irrational use of medicine (Indian Pharmaceutical Associations, 2005). In most developing countries, the majority of decisions to treat with drugs are taken without consultation with a medical doctor. The crucial role of private pharmacies is to be taken into consideration as well as the need to improve public education regarding drug use (FIP, 2000).

The use of pharmaceuticals also has an environmental aspect as, for example; the wide-spread use of self-medication with antibiotics usually implies too few tablets during a too short period, risking the development of antibiotics resistance (FIP, 2000). In 1985, the WHO convened the Conference of Experts on the Rational Use of Drugs in Nairobi, and defined the rational use of drugs as follows “*The rational use of drugs requires that patients receive medication appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community*” (WHO, 1985). The requirements of the rational use of medicines can be fulfilled only if the process of both prescribing and dispensing is appropriately followed. This includes steps concerned with proper

diagnosis, correct prescribing, dispensing, and giving proper information to the patient.

Rational use of medicine has been realized as one of the main concerns for the development of pharmaceutical sector in Indonesia. Since 2001, Ministry of Health (MOH) Republic Indonesia has a Directorate of Rational Use of Medicine.

#### **2.4 Quality of pharmacy service**

Pharmacy services are the provision or sale of pharmaceutical products by drug retailers (World Bank, 2006). Providing appropriate professional advice to patients is one of the core functions of community pharmacist's contribution to the maintenance of public health (Zhen et al., 2003).

Comprehensive pharmacy service involves activities both to secure good health and to avoid ill-health in the population. When ill-health is treated, it is necessary to assure quality in the process using medicines in order to achieve maximum therapeutic benefits and avoid untoward side effects (FIP, 1997).

FIP classify each of the four main elements of good pharmacy practice. These standards are described as follows (FIP, 1997):

##### **1. Promotion of health and prevention of ill-health**

- Facilities for confidential conversation that cannot be overheard by others;
- Provision of general advice on health matters;

- Involvement of personnel in briefings for specific campaigns to ensure coordination of effort and consistency of advice;
  - Quality assurance of equipment used and advice given in diagnostic testing.
2. Supply and use of prescribed medicines and other health care products.
- Reception of the prescription and confirmation of the integrity of the communication.
  - Assessment of the prescription by the pharmacist. This activity involves therapeutic aspects (pharmaceutical and pharmacological), consideration of appropriateness for the individual, and social, legal and economic aspects.
  - Assembly of the prescribed items includes sources of supply of medicines and other items; manufacture of medicines; storage; condition at time of supply to the patient; personnel involved; equipment required; facilities and workplace required; preparation and quality assurance of extemporaneous preparations; disposal of unused pharmaceutical products and pharmaceutical waste.
  - Advice to ensure that the patient or carer receives and understands sufficient written and oral information to derive maximum benefit from the treatment includes facilities for confidential conversation that cannot be overheard by others; information sources; procedures to be followed and the appropriate documentation of these procedures; competence of personnel involved.

- Following up the effect of prescribed treatments includes the procedure to be followed in regular, systematic evaluation of progress or outcomes of treatment for individual patients or for groups of patients; access to necessary monitoring equipment and facilities; quality assurance of monitoring facilities.
- Documentation of professional activities includes recording professional activities and pertinent data in a manner that allows access to comprehensive information; procedures for self-assessment of professional activities and quality assurance.

### 3. Self-care.

- Facilities for confidential conversation that cannot be overheard by others;
- Qualifications of personnel to be involved;
- The ways of correctly assessing need, (e.g, finding out who has the problem, what the symptoms are, how long the condition has existed, what action has already been taken, which medicines are already being taken);
- Efficacy and safety of products recommended;
- Timing of referral to the medical practitioner and methods of follow-up.

### 4. Influencing prescribing and medicine use.

- Quality of prescribing data provided to the pharmacist;
- The preparation of formularies on medicines;
- Contacts with physicians on individual prescribing;



- Evaluation of data on the use of medicines in medical and pharmaceutical practices;
- Assessment of promotional materials;
- Dissemination of evaluated information within a formal network;
- Educational programs for health professionals;
- Reference sources available to the pharmacist;
- Confidentiality of data relating to individual patients;
- Reporting of adverse events, medication errors, defects in product quality and detection of counterfeit products.

Many research worldwide assessed the standard of pharmacy service. In Lao PDR, Sykhang (2002) studied the practices of private pharmacies, the quality of drug and the effectiveness of government regulations in Savannakhet province. The measurement of this study for quality of pharmacy services was based on the concept of Good Pharmacy Practice. This study separated the quality of pharmacy services into facility indicators and dispensing indicators.

In Japan, Kamei et al. (2001) investigated the patients' demand for community pharmacy. They developed seven evaluation indices for pharmacy services. There are (1) Attitude of pharmacy/pharmacist, (2) Availability of OTC drugs, (3) Availability of special services, (4) Facilities, (5) Convenient location, (6) Convenient hours, and (7) Medication Record.

In Indonesia, a standard of pharmaceutical services in pharmacy has been made by Directorate of Clinical and Community Pharmacy, Directorate General (DG) of

Pharmaceutical and Medical Devices with Indonesian Pharmacist Association Board in 2006 (Ministry of Health [MOH-RI], 2006a). The standard has been made to protect the people from unprofessional services, to protect the pharmacist from the improper suit from the people, as a guideline in pharmaceutical practice's monitoring, and to build and increase the pharmaceutical services in pharmacy.

Purwanti et al. (2004) studied the description of pharmaceutical services in community pharmacy in Jakarta, Indonesia. With 65 sample sizes, she used the standard from Directorate of Clinical and Community Pharmacy, DG of Pharmaceutical and Medical Devices. She divided the Standard into 4 fields of pharmaceutical services in pharmacy; non-prescription drugs services, communication-information-education services, prescription drugs services and drug-management.

## **2.5 Indonesia**

### **2.5.1 Indonesia Geographic and Demographic Situation**

Indonesia is the largest archipelago in the world, lies between two continents, Asia and Australia, and two oceans, Pacific and Indian Oceans. With the total area of 1,890,754 km<sup>2</sup>, it consists of 17,508 islands, of which around 6,000 are inhabited. The five main islands are Sumatra (473,606 km<sup>2</sup>), Java/Madura (132,107 km<sup>2</sup>), Kalimantan (539,460 km<sup>2</sup>), Sulawesi (189,216 km<sup>2</sup>), and Papua (421,981 km<sup>2</sup>).

The country is divided into 33 provinces and 440 districts/municipalities. There are 300 ethnic groups, five major religions, 583 local languages, and one national language – 'Bahasa Indonesia'.

The estimated total population in Indonesia in year 2006 is 222.05 million (WHO-SEARO, 2007). It's population density 116 per km<sup>2</sup>. From the total population, about 58% of the population lives on the island of Java and the average density in this island is 700 per km<sup>2</sup>. The highest density is in Jakarta with 12,308 per km<sup>2</sup>. Approximately 29% of the population is in the category of young age (0-14 years). About 50% are productive age and only 4% consist of population of more than 65 years old (MOH-RI, 2006b). The Gross National Income (GNI) in 2006 is US\$ 1,410 (World Bank, 2007).

Jakarta is the country's capital. Located on the north of west Java, with 740.29 km<sup>2</sup>, its divided into 5 administrative municipalities and 1 district. Population in the city is 9,111,671. Three major cities surrounding Jakarta are Bekasi City on the east, Tangerang City on the west, Bogor City on the south, and another small city between Jakarta and Bogor, called Depok City.

Table 1: Jakarta Areas and Populations.

No	District/City	Area (km <sup>2</sup> )	Number of People
1	Seribu Islands District	11.81	19,362
2	Central Jakarta City	47.90	891,778
3	North Jakarta City	142.20	1,452,285
4	West Jakarta City	126.15	2,130,696
5	South Jakarta City	145.73	2,053,684
6	East Jakarta City	187.73	2,413,875
Total		661.52	8,961,680

Source : Jakarta Provincial Government, 2007

As the capital of Indonesia, Jakarta always becomes a barometer for all over the country. Not only is the economic wheel of the state, but Jakarta also the place where the central government is being held.

East Jakarta Municipality has 26.9% of total Jakarta's population. The main characters of East Jakarta are dominated by housing complex and residential area. As the main objective is based on the pharmacy in community and East Jakarta has the largest population among others municipalities, we choose East Jakarta for the target for this study.

Table 2: Population by Sub-Districts in East Jakarta

<b>"Kecamatan" Sub-Districts</b>	<b>Area (Km<sup>2</sup>)</b>	<b>Number of People</b>
<b>Pasar Rebo</b>	12.94	146,707
<b>Ciracas</b>	16.08	198,119
<b>Cipayung</b>	27.36	115,571
<b>Makasar</b>	21.64	170,455
<b>Kramat Jati</b>	13.34	200,750
<b>Jatinegara</b>	10.64	263,447
<b>Duren Sawit</b>	22.80	313,771
<b>Cakung</b>	42.47	211,447
<b>Pulo Gadung</b>	15.61	279,562
<b>Matraman</b>	4.85	194,864
<b>Total</b>	<b>187.73</b>	<b>2,094,693</b>

Source: Statistics DKI Jakarta Provincial Office

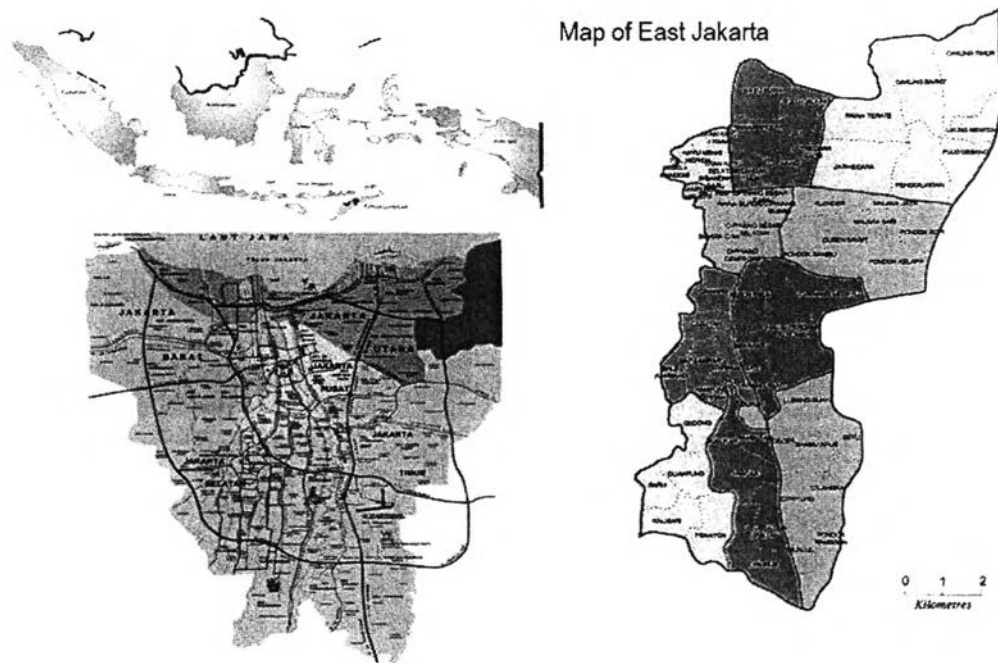


Figure 2: Map of Indonesia, Jakarta and East Jakarta

### 2.5.2 Health Care System in Indonesia

Indonesia's constitution in 1945 characterized health as a means to the promotion of public welfare and the development of human capital – as a national priority. Over the years, the Government has taken various steps in this direction and has greatly improved the public health of the country.

Although health development in Indonesia is growing steadily, the Indonesian health indicator in the World Health Report 2000 for “Health System Improving Performance” still consider as low. The result for this report ranks Indonesia as the 106<sup>th</sup> from the 191 country member of WHO (MOH-RI, 2004).

Health expenditure in Indonesia is 2.7 % of GDP or Gross Domestic Product (WHO, 2007b). Government expenditure on health is 34%, and 64% is private (WHO-SEARO, 2007). From private expenditure, 74% is out-of-pocket

expenditure (WHO-SEARO, 2007). The WHO suggested the health expenditure should be at least 5% of GDP (MOH-RI, 2004).

Health care system in Indonesia includes public hospitals, government health centers, and private hospitals and clinics. In an effort to provide health services for the poor, government has subsidized budget by giving free medical services in government health centers for primary medical services and hospitals for secondary or referred medical services.

In the Indonesian cabinet, the Ministry of Health (MOH) is responsible for the formulation and implementation of national health and overall administration, and the coordination and management of the country's health and welfare system.

In March 2006, the MOH issued a new strategic Plan 2005 – 2009 emphasizing the new vision “self-reliant communities to pursue healthy live” and its mission “to make people healthy”. The values underlying the vision and mission include: being people oriented, providing rapid and appropriate response, and fostering team work, high integrity, transparency and accountability.

### **2.5.3 Pharmaceutical Sector in Indonesia**

Drugs are not only costly inputs into health care services, but their availability tends to promote trust in those services. They make the pharmaceutical services differs substantially from other markets. In many low-income countries over half of all drugs are sold through the private pharmaceutical market (Bennett et al., 1997).

In Indonesia, pharmaceutical market is consist of 3 main actors: 1) pharmaceutical factories, 2) public as the user, and 3) traders or intermediaries that include distributors, dispensaries, drug stores and paramedics including physicians. The role of government also puts some interference as the regulator for pharmaceutical system.

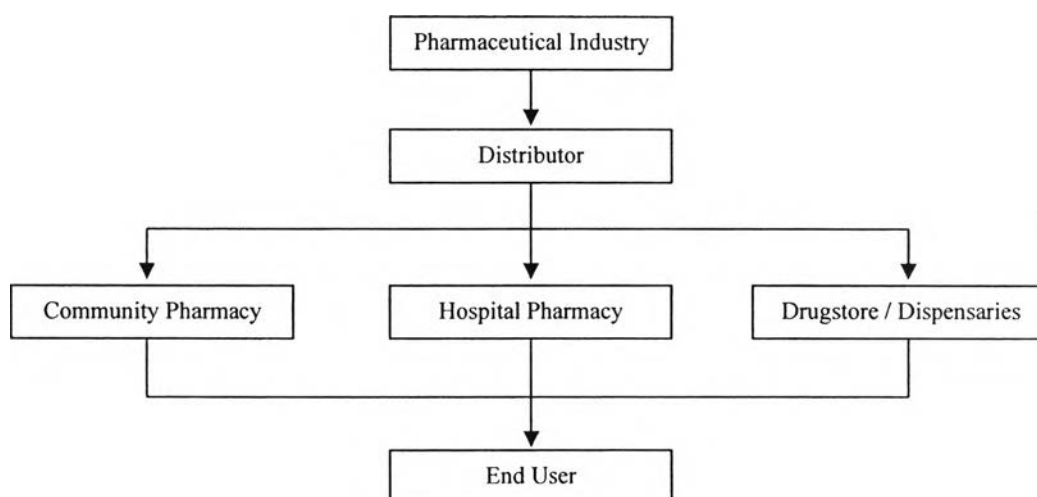


Figure 3: Distribution Channel of Medicine

The pharmaceutical manufacturers in Indonesia are consisting of state owned companies, private national companies and multinational companies. State owned pharmaceutical companies produce mostly generic medicines to support the government program to provide low price medicines for low income group. Using both local and central government budget, these generic medicines are distributed through local health care centers (*Puskemas*), other dispensaries and hospitals. A 1989 ministerial decree made prescribing and dispensing of generic drugs compulsory in public health facilities and encouraged the use of generic drugs in the private

sector. The Ministry of Health initiated a campaign to promote generic drug use by health professionals and the community.

In Indonesia, a pharmacist should have personal license to be able to work as a pharmacist. As a prerequisite, the license can be obtained after 3 years working outside the capital of the province. After get the license from the Ministry of Health, the pharmacist can work in the capital city of each province.

To establish a community pharmacy, another license is required. The license for a community pharmacy is under the authority of District Health Offices. One of the requirements is a pharmacist who must be responsible for the community pharmacy. But in reality, not all community pharmacies always have a pharmacist in the store during the opening hours. The shortage of pharmacist and the presence of pharmacist assistants who can do most of the supplying system is the main reason of the pharmacist absence in the community pharmacy. Also the role of pharmacist in the community pharmacy for pharmaceutical care is not the people awareness.

Increasing price of medicines has forced low income earners to find low price medicines. Usually they could find some 10-20% lower price of medicines of the same brands in dispensaries or drugstores. These drugstores offer OTC drugs as well as ethical drugs which are prescribed by physicians. By regulation, they are not allowed to sell ethical or prescription drugs which should be sold by prescription of physicians.

Providing drug information to the patient for the pharmacist in Indonesia is far from expectation. The practice of pharmacists in almost all pharmacies in



Indonesia is still “drug oriented” (Handayani, et al., 2006). Although the pharmacist realized the paradigm shifted from drug oriented into patient oriented, many factors including discontinuing education, no consultation fees, and low basic salaries for pharmacists in the community pharmacies are some of the reasons why the pharmacist in Indonesia not willing to practice as a drug counselor.