GENERIC MEDICINES: PERCEPTIONS OF PHYSICIANS, PHARMACISTS, CONSUMERS, FINAL YEAR MEDICAL AND PHARMACY STUDENTS IN IRAQ

By

ADHEED KHALID SHARRAD AL-SHARRAD

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

2011

DEDICATION

My late father

Mr. Khalid Sharrad who had inseminated the true values of knowledge in my life. May Allah forgive him and bring him rest in eternal peace.

My mother

Whose loves constant moral support, knowledge insight, and always prayerful approach towards ALLAH makes this day possible.

MY wife Aliaa

I would personally like to thank you for all your patience, consideration, support and love during the four years that I need to finish this thesis.

And

I also dedicate my thesis to my children Rand, Mohammed and Mustafa who helped me to be strong and continue my path for the future.

Adheed Khalid
2011

ACKNOWLEDGEMENT

In the Name of Allah, the Most Gracious, the Most Merciful

First, and foremost, I would like to thank almighty Allah for giving me the strength to complete my PhD studies. I am very grateful to Universiti Sains Malaysia (USM) for providing me to undertake my PhD studies for the last three years. To my supervisor, Associate Professor Dr Mohamed Azmi Ahmad Hassali, I am really grateful for giving me the opportunity to work with you. Personally, I am totally amazed with your tireless enthusiasm in guiding me for the successful completion of this project.

My cordial gratitude to all the staff and post graduate students at Discipline of Social and Administrative Pharmacy, School of Pharmaceutical Sciences, Universiti Sains Malaysia for their support throughout my study period.

I am profoundly grateful to my field advisor Professor Mazin AL-Hawaz from University of Basra /college of Medicine who provided me with his professional opinion, and imperative comments. His help and time is highly appreciated.

I also wish to acknowledge my friends in Malaysia, who were always with me including, Zaid Shaker and his wife Hala, Muhammad Zuhair, Muhammed Abu Al-Aaali and his wife Khansaa and my friend from Libya, Ramadan and mokhtar and my friend from Pakistan,Shazia.

TABLE OF CONTENTS

List of Tables

LIST OF FIGURES

LIST OF APPENDICES

LIST OF PUBLICATIONS

Journal publications

1. **Sharrad, AK,** Hassali, MA, Shafie AA. (2009) Generic medicines: Perception of Physicians in Basrah, Iraq, *Australasian Medical Journal,* 1(8), 58-64.

2. **Sharrad, AK ,** Hassali MA, Shafie AA (2010) Generic Medicine: Perceptions of pharmacists in Basra, Iraq. *Healthmed*, 4(1), 38-44. (Impact factor 0.2)

3. **Sharrad, AK,** Hassali, MA. (2011) Consumer perception on generic medicines in Basrah, Iraq: Preliminary findings from a qualitative study. *Research in Social and Administrative Pharmacy,* 7, 108-112. (Impact Factor 0.6)

4. **Sharrad, AK,** Hassali MA (2011) Knowledge and Perceptions of Final Year Medical Students in Iraqi Universities about Generic Medicines. *Journal of Bioequivalence and Bioavailability*, 3(5): 86-91

LIST OF ABBREVIATIONS

AARP	American Association of Retired Person
ACAI	Arab Company for Antibiotic Industries
B.Sc	Bachelor degree
CME	Continuing Medical Education
DOH	Directorates of Health
EGA	European Generic Medicines Association
FDA	Food and Drug Administration
GMP	Good Manufacturing Practice
INN	International Non-propriety Name
NDQCL	National Drug Quality Control Laboratories
PHC	Primary Healthcare Centres
PhD	Doctor of Philosophy Degree
SDI	Samara Drug Industry
TGA	Therapeutic Good Administration
WHO	World Health Organization

UBAT GENERIK: PERSEPSI PENGAMAL PERUBATAN,AHLI FARMASI, PENGGUNA, PELAJAR TAHUN AKHIR JURUSAN PERUBATAN DAN FARMASI DI IRAQ

ABSTRAK

Ubat-ubatan generik memberikan suatu peluang penjimatan dalam perbelanjaan penjagaan kesihatan bagi pihak kerajaan dan juga para pengguna. Dalam konteks ini, tiada kajian dijalankan di Iraq berhubung persepsi dalam kalangan doktor, ahli farmasi, pengguna serta bakal pengamal perubatan (seperti pelajar perubatan dan farmasi) tentang pempreskripsian, penukar-gantian serta penggunaan ubat-ubatan generik. Justeru, tesis ini bermatlamat untuk mengkaji persepsi serta pengetahuan yang ada pada pengamal perubatan, farmasi serta para pengguna megenai kualiti penggunaan ubat-ubatan generik di Iraq. Dalam usaha mencapai matlamat ini, kaedah kualitatif digunakan.

Sepuluh orang doktor telah ditemu bual. Analisis daripada kandungan temu bual mengenal pasti tujuh (7) tema utama: amalan mempreskrib ubat, pengetahuan tentang kesamaan terapeutik daripada ubat-ubatan generik, penerimaan pesakit terhadap ubat-ubatan generik, ubat-ubatan tiruan, sumber maklumat tentang drug/ubat serta pengaruh iklan drug/ubat terhadap pilihan ubat, amalan menukar-ganti jenama oleh ahli farmasi komuniti, serta strategi untuk meningkatkan penggunaan ubat-ubatan generik.

Sepuluh orang ahli farmasi turut ditemu bual. Dapatan temu bual mengenal pasti lima (5) tema utama: amalan menukar-ganti ubat generik, pengetahuan tentang perubatan generik, kualiti dan keselamatan ubat-ubatan generik, didikan pesakit oleh ahli farmasi

tentang ubat-ubatan generik dan strategi untuk meningkatkan kegunaan ubat-ubatan generik.

Seramai empat belas (14) orang pengguna ditemu bual untuk meninjau pendapat mereka tentang isu-isu berkaitan penggunaan ubat-ubatan generik. Analisis daripada temu bual mengenal pasti lima (5) tema utama: pemahaman istilah ‘‘ubat-ubatan generik,’’ keutamaan terhadap ubat-ubatan generik, penolakan terhadap ubat-ubatan generik, menukar-ganti generik, dan mendidik pengguna tentang penggunaan ubat-ubatan generik.

Berdasarkan natijah kajian yang dijalankan dalam bab 3, 4 dan 5 tesis ini, terutamanya kekurangan pengetahuan yang ketara dalam kalangan doktor dan ahli farmasi, maka pengetahuan dan persepsi tentang ubat-ubat generik ditinjau dalam kalangan bakal pengamal perubatan dan farmasi di beberapa buah universiti di Iraq. Untuk kajian ini, dua (2) soal selidik dijalankan. Bab 6 dan 7 mengutarakan metodologi dan dapatan kajian bagi dua (2) kajian ini. Analisis bagi respons daripada kedua-dua kumpulan menunjukkan bahawa terdapatnya kekurangan pengetahuan tentang ubat-ubatan generik, terutamanya dari aspek kesamaan biologi. Sebagai kesimpulan, tesis ini menonjolkan tentang kewujudan penghalang dalam penggunaan ubat-ubatan generik di Iraq, dari kaca mata doktor, ahli farmasi dan pengguna. Dalam usaha menangani masalah ini, tindakan perlu digarap untuk meningkatkan keyakinan tentang ubat-ubatan generik dalam kalangan pengamal penjagaan kesihatan. Hal ini boleh dicapai dengan memasukkan suatu silibus baru yang sesuai di peringkat ijazah pertama, yang menjelaskan tentang kesamaan biologi, keselamatan dan keefisienan ubat-ubatan generik.

GENERIC MEDICINES: PERCEPTIONS OF PHYSICIANS, PHARMACISTS, CONSUMERS, FINAL YEAR MEDICAL AND PHARMACY STUDENTS IN IRAQ

ABSTRACT

Generic medicines provide an opportunity for major savings in health care expenditure to both government and consumers Within this context, no studies have been conducted in Iraq regarding the perceptions held by physicians, pharmacists, consumers and future practitioners such as medical and pharmacy students towards the prescribing, substitution, and use of generic medicines Therefore, the aims of this thesis were to investigate perceptions and knowledge held by both the healthcare providers and consumers toward the quality use of generic medicines in Iraq. In order to reach these aims, qualitative methods were used.

Ten physicians were interviewed. Thematic content analysis of the interviews identified seven major themes: medicine prescribing practices, knowledge of therapeutic equivalency of generic medicines, patients' acceptance of generic medicines, counterfeit medicines, source of information on medicines and the influence of drug advertising on the choice of medicine, brand substitution practices by community pharmacists, and strategies to improve the usefulness of generic medicines.

A total of ten pharmacists were also interviewed. Five major themes emerged: generic medicines substitution practices, knowledge about generic medication, quality and safety of generic medicines, patient education by pharmacists regarding generic medicines and strategies to improve generic medicine utility.

A total of fourteen consumers were interviewed in order to explore their opinion towards issues related to generic medicines use. Thematic analysis of the interviews identified five major themes: understanding of the term ‘‘generic medicine,’’ preference for generic medicine, refusal of generic medicine, generic substitution, and educating the consumers on the use of generic medicines.

Based on the outcomes of the studies conducted in chapter 3, 4 and 5 of this thesis, particularly the apparent knowledge deficits of physicians and pharmacists, the knowledge and perceptions of generic medicines were explored among future medical and pharmacy practitioners in several universities in Iraq. For these studies, two questionnaire surveys were conducted. Chapter 6 and 7 of this thesis present the methodology and the study findings for these two surveys. Analysis of the Responses for both groups indicated that there is also a lack in knowledge regarding generic medicines, especially on the aspects of bioequivalence. In conclusion, this thesis highlights the existing barriers to the usage of generic medicines in Iraq from the points of view of physicians, pharmacists and consumers. In order to overcome these barriers, actions are needed to elevate confidence in generic medicines among healthcare practitioners. This can be achieved by providing appropriate topics at the undergraduate level, clarifying bioequivalence, safety and efficacy of generic medicines which appears to be currently lacking.

CHAPTER ONE: GENERAL INTRODUCTION

1.1 Introduction

The increasing price of medicine is a phenomenon that affects all countries across the world (Birkett *et al.*, 2001; Dickson, 1992; Donelan *et al.*, 1999; Ess *et al.*, 2003; Kanavos, 1999; Ping *et al.*, 2008; Shafie and Hassali, 2008). Using low cost generic medicines is one of the mechanisms undertaken by many health policy makers around the world in order to alleviate this problem (King and Kanavos, 2002a; Laing *et al.*, 2001; Moulds, 1992; Nilsson and Melander, 2000; Smeaton, 2000; Tatchell, 2003).

Innovator medicines are more expensive than generic medicines. Generally, generic brands cost between 30-75% less than innovator brands (Carroll, 1995; Karim *et al.*, 1996b; Lieberman, 1986; Lofgren, 2004a; Yarnall, 1994). Two reasons for this lower cost are, firstly, that generic medicine producers do not need to spend huge investment on research and development and marketing of a new drug entity (Kirking and Ascione, 2001; Kirking *et al.*, 2001a; Nuss *et al.*, 2004; Weaver, 1989), and the second reason is competition; when a number of manufacturers produce the same generic medicine, competition among these manufacturers can drive the price down (Lofgren, 2004a; Lofgren and Boer, 2004; McGavock, 2001a; Stevens *et al.*, 1993).

1.2 Definition of generic medicines

The term 'generic medicine' may be defined in different ways. It can mean a product marketed under the drug's approved international non-proprietary name (INN), or it can also mean a product marketed under a different brand (proprietary) name. The World Health Organization (WHO) defines 'generic medicine' as 'a pharmaceutical product, usually intended to be interchangeable with the innovator product, marketed after the expiry of patent or other exclusively right'(WHO, 2005b). In some

countries, they may be marketed in dosage forms and/or strengths different from that of the innovator products (Staff and Salud, 2004).

According to the European Generic Medicines Association (EGA), a generic medicine is defined as ‘a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bio-equivalence with the reference medicinal product has been demonstrated by appropriate bio-availability studies’ (Donovan, 2003). A generic medicine is marketed in agreement with the patent law and is recognized either by its own brand name or by its internationally approved proprietary scientific name. A generic medicine is of the same efficacy, safety and quality as the original brand name product and undergoes rigorous testing before it is licensed and given market approval (Bongers and Carradinha, 2009).

In the United States, the Food and Drug Administration (FDA), which is an American organisation responsible for registering and marketing authorisation for medicinal products, defines generic medicine as ‘a medicine that is identical, or bioequivalent, to a brand name medicine in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use’ (USFDA, 2002).The Therapeutic Good Administration (TGA), which is the regulatory body for registering and licensing medical products in Australia, defines generic medicine as ‘medicine which has the same qualitative and quantitative composition in term of active principles, same pharmaceutical form and bioavailability have been carried’(TGA, 1994). In terms of basic generalisation, generic medicines should not use a commercial brand name when marketing, but use international non-proprietary name (INN), in practice, generics can be categorically classified as branded generics,

which means copies of pharmaceutical specialties with their own brand, semi-branded generics, which means products marketed only under the INN followed by the name of the manufacturer, and unbranded generics, which are medicines marketed under the INN (Garattini and Tediosi, 2000).

1.3 The naming process of medication

Each pharmaceutical substance is specified by an international non-proprietary name (INN) or a generic name (Staff and Salud, 2004). Physicians and pharmacists use the generic name commonly and when a new drug is ready to be marketed the generic name is usually created (Gundersen, 1998). International non-proprietary names are generated by the World Health Organization (WHO) for all pharmaceuticals globally, using a procedure adopted by the executive board of the WHO (Staff and Salud, 2004). Each INN is a unique name that is internationally recognised and is public property (WHO, 2003). An important feature of the INN system is that the names pharmacologically related substances demonstrate their relationship by using a common 'stem', as shown in Table 2.1. This allows health care experts dealing with pharmaceutical products to recognise that the substance belongs to a specific group of substances with similar pharmacological activities (Staff and Salud, 2004).

Table 1.1 Generic names of common WHO approved stems

Stem	Class of drug	Generic name
-olol	B-adrenoreceptor antagonists	metoprolol, atenolol
-azepam	Benzodiazepine family	diazepam,clonazepam
-vir	Antiviral agents	acyclovir
-cillin	penicillin	amoxycillin
-bendazole	Antihelmintics (thiabendazole)	albendazole
-oxetine	Antidepressants	fluoxetine

The company that holds the patent for the drug can only produce and sell the brand name medication, usually on the basis that it can be recognised, pronounced and remembered by health experts and members of the public (Helen, 2009). The chemical name of a medication is a scientific name based on the chemical structure of the compound and this name may not be used to identify the drug under clinical situations (Kenagy and Stein, 2001).

1.4 Generic medicines in international markets

The spread of generic medicines is different in different international markets and this variation is due to the differences in generic medicine policies in the respective countries. Simoens and De Coster (2006) conducted a study to underline the need for generic medicines markets development and the potential savings that can be achieved from the substitution of innovator medicine with its generic counterpart in a number of countries for which data were available. Underlining on the off-patent market, the top ten medicines were picked by the expenditure on innovator medicines in 2004. As these medicines showed the top expenditure on innovator medicines, they would be expected to make the biggest potential savings from generic substitutions. This study showed the savings that can be made if innovator medicines are replaced by generic medicines. Tables 2.2-4 show the top 10 active substances for Austria, France and the UK (Simoens and De Coster, 2006) .

Table 1.2 Potential savings from increased generic substitutions in Austria, 2004

No	Active substance	Public expenditure on originator medicines(£)	Savings from generic substitutions(£)
1	lisinopril	33,545,548	7,973,247
2	ramipril	26,715,264	11,717,770
3	ciclosporin	22,456,438	3,545,505
4	amlodipine	22,379,694	3,701,259
5	metoprolol	22,017,335	9,580,570
6	carvedilol	21,043,749	2,998,096
7	pravastatin	19,565,709	5,364,850
8	lamotrigine	17,006,227	5,539,110
9	enalapril	16,588,539	2,183,517
10	omeprazole	16,292,170	5,358,914
Total		217,610,673	57,962,838 (27%)

Table 1.3 Potential savings from increased generic substitution in France, 2004

No	Active substance	Public expenditure on originator medicines(£)	Savings from generic substitutions(£)
1	omeprazole	446,515,016	117,723,086
2	paracetamol	145,522,610	23,838,883
3	paroxetine	137,898,121	45,042,899
4	ethinylestradiol	137,520,042	101,370,687
5	bisoprolol	135,870,312	60,368,156
6	hydrochlorothiazide	115,174,757	41,624,759
7	citalopram	101,443,283	38,817,197
8	trimetazidine	100,035,279	35,760,821
9	fenofibrate	97,599,601	38,537,643
10	gliclazide	92,798,116	22,206,603
Total		1,510,377,137	525,290,734 (35%)

Table 1.4 Potential savings from increased generic substitution in United Kingdom, 2004

No	Active substance	Public expenditure on originator medicines(£)	Savings from generic substitutions(£)
1	pravastatin	173,926,201	1,827,32
2	doxazosin	167,861,096	120,582,878
3	beclomethasone	141,198,568	8,721,002
4	simvastatin	130,721,082	36,535,810
5	nifedipine	93,826,729	40,906,097
6	budesonide	88,848,854	30,632,531
7	omeprazole	79,995,288	28,369,791
8	fentanyl	73,644,518	67,750,188
9	gabapentin	60,788,304	1,526,222
10	paroxetine	59,976,234	12,993,094
Total		1,070,786,874	349,844,935 (33%)

These tables indicate that an increased substitution of generic for originator medicines could yield substantial savings for the top 10 active substances when considering the expenditure on originator medicines.

Sheehan (2002) stated that generics made up around 47 % of all prescriptions filled in the UK in 2001; however, it all represented 18 % of the total consumer spending on prescription drugs. Table 2.5 shows shares of generics in the prescription medicine market in selected countries in 2001 (Sheehan and Sweeny, 2002). King and Kanavos (2002) observed that the rate of generic penetration, when measured as a percentage of total spending on pharmaceuticals, has a lower percentage than the percentage of sales volume. This is due to the low prices of generic medicines when compared to originator products (King and Kanavos, 2002a).

Table 1.5 Shares of generics in the prescription medicine market in selected countries in 2001

Country	Share of generics in prescription medicine market in 2001 (%)	
	By number of scripts	By value
USA	45	8.4
Australia	18.9	9.6
UK	47	18
Germany	40	28
Denmark	60	35

1.5 Bioequivalence and bioequivalence testing

Generic medicines are often substituted for innovator medicines by pharmacists in an effort to decrease the cost of medicines. Generic substitution is allowed and encouraged in most cases, provided that the generic formulation is accepted as therapeutically equivalent to the innovator formulation by the FDA (Balthasar, 1999).

Generally, before a new generic formulation of an innovator medicine can be marketed, the pharmaceutical manufacturer must prove that its action will be essentially the same as the innovator formulation. The purpose of testing a generic medicine is not to demonstrate the clinical usefulness of the drug but to ensure that the generic medicine has the same relative bioavailability and bioequivalence to the innovator product (Pearce *et al.*, 2004).

The term 'bioavailability' is defined as 'the degree to which, or the rate at which, a medication or other substance is absorbed or becomes available at the targeted place in the body' (Pearce *et al.*, 2004). Bioavailability can be affected by inactive ingredients in the medicine, such as additives that prevent the medication from dissolving in the stomach (Purse 2006).

'Bioequivalence' is defined as 'the rate and extent of absorption of the test drug that does not show a significant difference from the rate and extent of absorption of the reference drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses' or 'the extent of absorption of the test drug does not show a significant difference from the extent of absorption of the reference drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the reference drug in the rate of absorption of the drug is intentional, is reflected in its proposed labelling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug' (Balthasar, 1999). The term 'pharmaceutical equivalents' refers to drug products that contain identical amounts of identical active drug ingredients, that is, the same salt or ester of the same therapeutic moiety, in identical dosage forms, but not necessarily containing the same inactive ingredients (Birkett, 2003; Nation and Sansom, 1994; TGA, 2002). Drug products are considered to be 'therapeutic equivalents' only 'if they are pharmaceutical equivalents and they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labelling (Balthasar, 1999; Leslie, 2002).

1.5.1 Determining bioequivalence

The typical design employed in bioequivalence studies is the two-treatment, two-period crossover design (Figure 2.1). In this design, subjects are randomly separated into two groups of same numbers. In the first study period, the innovator formulation is administered to group 'A', and the test formulation is administered to group 'B'. Cross-over design is used in the second period of the study after a separated washout period which is designed to be of a sufficient duration to allow elimination of the drug administered in the first period. The subjects are split into two groups to let recognition of 'period' or 'sequence' effects in the study results (Balthasar, 1999).

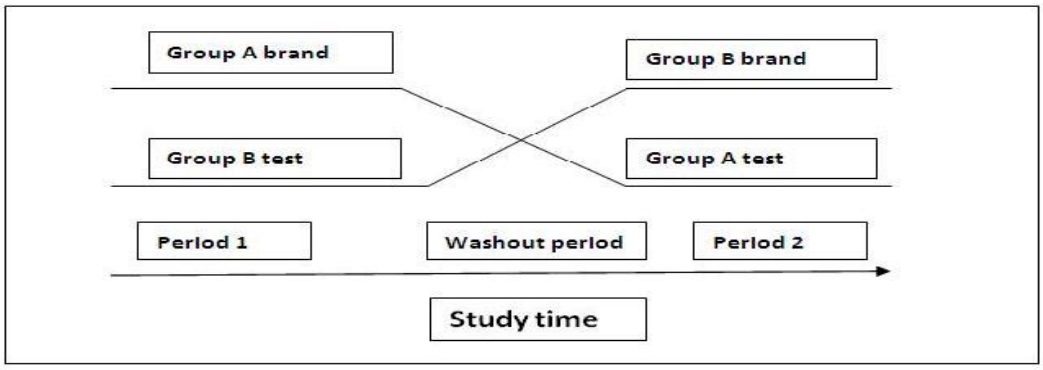

Figure 1.1 Schematic representation of the standard two-treatment crossover study design commonly employed in bioequivalence trials

This procedure is usually carried out by calculating a 90% confidence interval that is constructed around the ratio of the test and reference drugs by means of two one-sided test procedures. To show bioequivalence, 90% confidence interval limits are required in the range of 80-125% based upon a logarithm of transformed AUC and C_{max} data. This is commonly referred to as 80% / 125% 'goalposts' for the average bioequivalence criterion, and has been adopted by most of the drug regulatory bodies throughout the world (Dentali *et al.*, 2011; Meredith, 2003; USFDA, 2009).

1.6 Iraq: A Historical background

Iraq lies in the Middle East bordering Turkey, 352 km; Jordan, 181 km; Syria, 605 km; Kuwait, 240 km; Saudi Arabia, 814 km; and Iran, 1458 km (Harris, 2007). Iraq's capital city is Baghdad and it is located in the centre of the country. Al-Basra in the south and Mosul in the north are other major cities (Harris *et al.*, 2007).

Figure 1.2: Map of Iraq

Iraq's territory constitutes of four major regions: desert in the western and south western parts, rolling uplands surrounded by the rivers Tigris and the Euphrates,

mountains in the northern and north eastern parts, and alluvial plains in the central and south eastern parts through which the two rivers flow (WHO, 2006).

Iraq's area varies in different citations as between 433,970 square kilometers and 437,393 square kilometers. However, the Iraqi official statistical reports sums up the area of the country as 438,446 square kilometers (WHO, 2006).

Estimates put the population of Iraq as 27.1 million. According to the survey done in 1977, the population was 12 million and this number increased in 1987 to reach 16.3 million. In the 1997's survey, the population was found to be 22 million (almost double the number of that of that in 1977). A 3% overall population growth has been estimated during the period of 1987-1997. As a follow-up to the world summit for children, a national report was issued noting that the total population had reached 23.1 million by the year 2000 with an estimated growth rate at 2.94 million (WHO, 2005a).

"Males constitute 50.2% of the population, children below 5 years of age constitute about 17% of the population, children under 15 almost 40.5 percent, and those of adolescent age (10-19 years) form about 23% of the population. Women at childbearing age constitute about 22% of the population. Those who are 60 years old and 65 years and above form 3.8% and 2.8 % of the total population, respectively. More than 24% of the population lives in Baghdad, 9.5% in Mosul, 6.6 % in Basra, 5.2% in Erbil, and 6.3% in Sulaimaniya. Two thirds of the population (67.1 %) live in urban areas and one third in rural areas. Around 97% of the population are Muslims. The remaining 3% is made up of Christians and other religious groups. The Kurds, descendants of Indo-European tribes who settled in Iraq in the 2nd century

B.C., make up 15-20 % of the population. Arabic is the official language, but Kurdish, Assyrian, and Armenian are also spoken (WHO, 2005a).

Regarding the climate, Iraq in summer has a constant north-westerly wind (shamal), while in winter a strong south-easterly air current (sharqi) develops. The highly hot and dry summers start from May to October, and during the hottest time of the day- often reaching 49°C in the shade. Winters, starting from December to March, are humid and moderately cold, with temperatures averaging about 10°C. Normally, no rain falls from the end of May to the end of September. With annual rainfall of less than 38 cm (15 in), agriculture is dependent on irrigation (Iraq, 2011).

1.6.1 Overview of Iraqi health care system

In the early 1920s, the Iraqi modern health system saw its first light. Iraq's first government established the Ministry of Health (MOH), which after a couple of years became a part of the Ministry of Interior until 1939, when it became a part of the Ministry of Social Affairs. This continued until 1952, when a new Ministry of Health was re-established and continues to the recent time. Since the early decades of the 20th century, the MOH went through various organizational structures. The latest structure was adopted after the recent war in 2003, and is meant to see further modifications.

Providing the Iraqi people with health care is the responsibility of the MOH. After the 2003 war, the MOH started to receive its funding from the Ministry of Finance. However, the given funds are barely enough to cover staff members' salaries with

some minor funds for the purpose of covering other recurrent expenses (Izdihar, 2006).

Public Clinics, is the name of a specialist directorate in the MOH providing the public with curative care at subsidised prices for a period of three hours a day in the afternoon, outside the official working hours of public facilities. The directorate of Public Clinics utilizes the buildings of many primary health care centres in order to provide these services (Izdihar, 2007).These clinics play a great role in the delivery of drugs to patients with chronic diseases, through a drug card carried by the patients, on a monthly basis. These clinics are completely independent facilities and cover all of their expenses and payments through patients' capitation fees. Some of their profits might be forwarded to the Ministry of Finance. The clinics recruit their staff independently either from MOH staff or retired or private practitioners. Private hospitals are licensed and monitored by the MOH. Private clinics and pharmacies are supposed to be licensed by medical syndicates.

The Ministry of Health owns a trading company called KIMADIA. Established in 1966, two thirds of KIMADIA's work involves the importation, storage and distribution of drugs and medicine supplies. The KIMADIA system controls all the imported medicines into Iraq (both public and private). Random samples are taken from each batch and are sent for testing to the National Drug Quality Control Laboratories (NDQCL). Once the batch passes the test, the NDQCL informs the department of planning in MOH/KIMADIA in order to prepare for the planning of distributing this item to the governorate's Directorates of Health (DOHs).

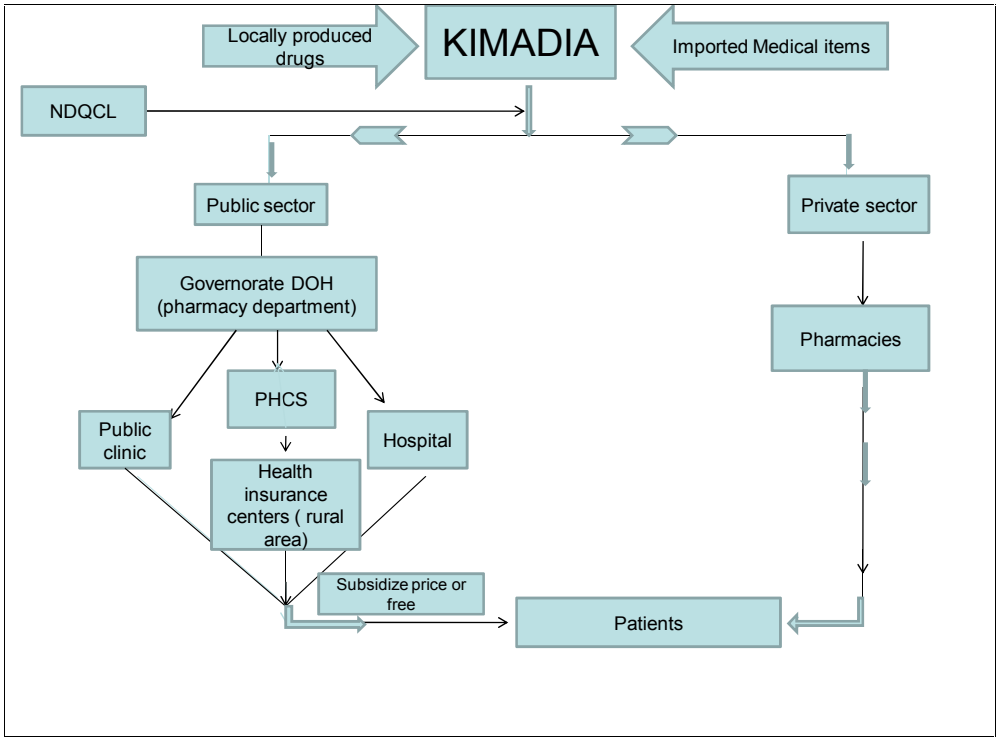

Figure 1.3: The Stages of MOH/KIMADIA Drug Distribution System

For more than two decades, KIMADIA has been the only authorized body by law to manage, plan, select, quantify, procure, store and distribute medicines and medical equipment. In 1989, it was estimated that 70% of the drugs were imported. The Samara Drugs Industries (SDI) covers the remaining 30%, counting 160 different dosages and forms.

Public and semi public sectors dominated the supply of medicines until the year 1994.Most of drugs (90%) were made available by using the public budget and were allocated to the public and semi-public sectors. According to Iraqi law, the KIMADIA system must market all drugs. After 1994, the private practice has been assisted by the Iraqi government and 700 new pharmacies have been opened. In addition, private pharmaceutical manufacturers such as the Arab Company for Antibiotic Industries (ACAI) and 18 other small plants are reportedly producing a wide variety of drugs and medical supplies (Izdihar, 2007).

The cost of health services were heavily subsidised by the Iraqi government in the 1980s, this includes providing free drugs and other hospital consumables. Currently, medicines are imported by KIMADIA from well-known companies and then distributed to the public sector at subsidised prices. On the other hand, the private sector imports and distributes medicines to both the private and public sectors at commercial prices.

1.6.2 The use of generic medicines in Iraq: A brief overview

Generic medicines are available in Iraq and are widely used in the public and private sectors. Brand substitution has been common practice for some time due to the shortage in brand medicines caused by the United Nation (UN) embargo, which has been in place since 1990 (Izdihar, 2007). At present, no legislation exists regulating brand substitution in Iraq. Iraq needs a new policy designed to regulate the importation of generic medicine from well-known sources in order to improve the bad image which has previously been held by patients as well as physicians and pharmacists regarding generic medicines.

1.7 Statement of the problem

Concerns have been expressed across the globe about the perceptions of generic medicines among physicians, pharmacists and consumers. The absence of information with regard to generic medicines, and their dispensing, prescribing and utilisation, is a problem in Iraq. There are no databases available to provide any basic information, and no research studies have been conducted to highlight issues surrounding generic medicines utilization. This study is one such attempt to address the significant information gaps surrounding the issues of generic medicine use, especially in issues related to prescribing and dispensing. Furthermore, no studies

have been conducted linking the perceptions of final-year medical and pharmacy students to the issues surrounding generic medicines prescribing and generic medicines substitution. In order to encourage the use of generic medicines in Iraq, a clearer understanding of the perceptions of physicians, pharmacists and consumers regarding generic medicines is required. In addition, an understanding of the perceptions held by final-year medical and pharmacy students is important, because their knowledge and approaches at this stage of their careers will influence their behaviour in the future regarding the prescription and substitution of generic medicines.

This current research is an attempt to address this problem by means of both qualitative and quantitative approaches.

1.8 Rationale of this study

Although generic medicines have been available over the past 20 years in the Iraqi medicine market, the current utilisation of generic medicines and brand substitution in Iraq is still unclear. To the best of knowledge and from through literature search, no study has been conducted or documented in Iraq to identify consumers' levels of acceptance, perceptions or understanding of the use of generic medicines or brand substitution. Indeed, the impact of generic prescribing by physicians and brand substitution by pharmacists on patients' understanding and safe use of their medication is yet to be fully explored. Therefore, this study was designed to investigate the factors affecting the use, prescription and substitution of generic medicines among consumers, physicians, and pharmacists in Iraq. In-depth interviews were conducted with participants from each of these groups in order to ascertain their perceptions and understanding of generic medicines. Based on the

outcomes of the interviews, further studies were undertaken involving final-year medical and pharmacy students in Iraqi universities in order to evaluate their knowledge and understanding of the issues surrounding generic medicine prescribing and substitution, which will have an impact on the future use of generic medicines in Iraq.

1.9 Objectives

This study consists of two main parts: the first part (using qualitative methods) is intended to explore and gather baseline information regarding the knowledge, attitudes and perceptions of physicians, pharmacists and consumers in Iraq towards generic medicines. Furthermore, this study has been conducted in order to determine the barriers faced by physicians, pharmacists and consumers regarding the use of generic medicines.

The second part of this study adopted quantitative method to evaluate and assess the perceptions and knowledge of the final-year medical and pharmacy students in some Iraqi universities towards issues surrounding generic medicine use.

The specific objectives of this study are:

1. To explore the knowledge, attitudes and perceptions of physicians towards generic medicines prescribing.
2. To evaluate the knowledge, attitudes and perceptions of pharmacists towards the generic medicines substitution.
3. To determine the barriers faced by physicians and pharmacists with regards to generic prescribing and dispensing.
4. To evaluate the knowledge, attitudes and perceptions of consumers towards the use of generic medicines and

5. To assess the knowledge and perceptions of final-year medical and pharmacy students in Iraqi universities towards issues surrounding generic medicine use.

1.10 Significance of the study

1. This study will document the importance of the acceptance of generics in Iraq by major stakeholder in Iraqi health delivery system.

2. This study will help to identify the issues influencing the prescribing, dispensing and use of innovator drugs compared to generics among physicians, pharmacists and consumers.

3. This study will provide baseline data to assist policy makers in Iraq for developing appropriate strategies to encourage the appropriate use of generic medicines, thus emphasising the need for a clear policy regarding generic medicines;

1.11 Overview of the thesis

Chapter 2, a thorough review of the literature which is relevant to this study was outlined and gaps in the present literature were discussed.

Chapters 3, 4 and 5 represent the qualitative phase of the study. The respective chapter provides information on the methodology and findings from qualitative interviews with a purposive sample of physicians, pharmacists and consumers in Basra, Iraq. Chapter 3 presents the findings from the interviews with physicians about the issues involved in generic prescribing and their knowledge of bioequivalence. Chapter 4 presents the findings from the interviews with pharmacists regarding the issues involved with generic medicine substitution. Chapter 5 presents the findings from interviews conducted with consumers about their perceptions of generic medicines.

Chapters 6, 7 and 8 describe the methodology and findings from quantitative surveys involving final-year medical and pharmacy students in some universities in Iraq. These surveys were designed to assess their knowledge and understanding of generic medicines, generic prescribing and generic substitution. Chapter 6 describes the findings of the self-administered survey conducted among final-year medical students in some universities in Iraq in order to assess their knowledge and understanding of generic medicines and generic prescribing. In Chapter 7, outcomes from the self administrated survey conducted among final year pharmacy students in some universities in Iraq about their knowledge and perceptions of generic medicines are discussed. Chapter 8 describes a comparative analysis of the knowledge and perceptions held by final-year medical students and final-year pharmacy students towards generic medicines using data from similar questions posed to both groups in their respective surveys.

Chapter 9 draws the thesis to a conclusion with an overall summary and a set of recommendations for further research.

CHAPTER TWO: LITERATURE REVIEW

2.1 Physicians' acceptance and understanding of generic medicines

Based on exhaustive literature review using standard database such as PubMed, Scopus, Google Scholar, Embase and Science Direct, using generic medicines, general practitioners, physicians, perception, and knowledge as keywords, there were no studies have been conducted in Iraq to explore physicians' perceptions of generic medicines. However, several such studies have been conducted in other developed countries with high generic medicines utilization especially the USA and UK.

One of the earliest studies concerning generic medicines was conducted in 1980 by Bearden *et al.* in The State of Alabama, USA (Mason and Bearden, 1980). This study focused on the attitudes about, the perceptions of, the knowledge of, and the satisfaction with generic medications and made comparisons between physicians, pharmacists, and consumers. It also explored the silent issues affecting the prescription of generic medicines by physicians, their dispensing by pharmacists and their use by consumers. Mailed questionnaires were used by the researchers in this study and responses were received from 412 physicians, 118 pharmacists and 105 consumers. All of the physicians responded that, in general, generic medicines produced the same therapeutic effect as the original versions. Furthermore, all physicians that participated in this study strongly agreed on that pharmacists should only hand out drugs produced by manufacturers using GMP (good manufacturing practice). The researchers concluded on the importance of educating physicians earlier in their careers about the benefits and importance of generic prescribing leading to an improved acceptance of generic drug practices (Mason and Bearden, 1980).

In another early study conducted in USA, Bower and Burkett (1987) reported findings from a nationwide survey of 317 medical practitioners in family practice. Their study reported that the percentage of respondents who have confidence in generic drugs and prescribe them in their regular practice was 63%. Correlations were recognised between the physicians' sources of drug information and their prescribing patterns. Generic drugs were mostly prescribed by physicians who were more commonly trained to be as residents, less dependent on drug companies' representatives and were readers of the New England Journal of Medicine. Nearly half of the respondents did not correctly differentiate all ten generic product names; there was a strong positive relationship between recognition of the generic-named products and the respondents' reported frequency of prescribing generic products in general. An awareness of generic names was highest for young, residency-trained, and board-certified family practitioners, who were more likely to read the Medical Letter and the New England Journal of Medicine and those who relied the least on journal advertisements (Bower and Burkett, 1987).

Shulkin (1991) carried out a study in Pennsylvania, USA. Questionnaires were distributed anonymously to a sample of convenience containing 63 medical practitioners in six Pennsylvania hospitals. The percentage of participants who thought that generic and brand-name medications had the same therapeutic effects was nearly 73 %. Although most participants reported prescribing brand-name rather than generic products in more than 50% of their prescriptions, they did not state on their prescriptions that the brand-name drug must be dispensed. Some differences according to specialty were seen: for example, psychiatry residents were more likely to prescribe brand-name drugs than surgery or internal medicine residents (Shulkin *et al.*, 1992).

Banahan and Kolassa, conducted a study in the USA involving a questionnaire that consists of five sections and 19 questions regarding attitudes, beliefs, knowledge and experience with generic drugs that was sent to 3639 physicians nationwide (Banahan and Kolassa, 1997). Attitudinal groups were identified by using cluster analysis and then analysed to study the differences in beliefs, knowledge, and experience with generic medicines. Furthermore, perception regarding the therapeutic index for 15 branded drugs and comfort in substituting those products with generic alternative were estimated.

In the study, two groups were identified: pro-substitution and anti- substitution. The anti-substitution group was further divided according to whether they felt more or less influenced by exterior pressures to substitute. Less than half (43%) of the respondents were categorised into the pro- substitution group, and they showed their strong support for the use of generic medication. In contrast, the anti- substitution group had strong feelings against this practice.

Physicians' views regarding generic drugs may be influenced by their level of knowledge of these drugs. A comparison can be conducted between two drugs having the same active ingredient (e.g., a brand- name product and a generic product) on the bases of the amount of variation in bioavailability permitted by the drug regulatory authorities for each drug. This type of knowledge is significantly important in the determination of the physicians' intentions in using generic drugs. When asking the participants about how much variation is permitted by the regularly authorities (FDA), the response of "don't know" was noted for 64% of the participants, while only 17% answered correctly (at the time of the study, FDA regulations generally considered two formulations to be bioequivalent if the rate and

extent of absorption of the generic product was between 80% and 125% of that of the brand product). The result gained from this study suggests that decisions regarding generic drugs taken by physicians were based on inaccurate perceptions. Regarding the therapeutic index for 15 branded drugs, the physicians in all groups identified similar products that they believed were not suitable for substitution. (Banahan and Kolassa, 1997).

Mcgavock conducted his study in the Republic of Ireland in 1997. A random sample of members of the Irish College of General Practitioners received a mailed questionnaire. This questionnaire focused on the concerns of Irish prescribers regarding generic prescribing. This study concluded that the low rate of generic medicine prescribing in Ireland, when compared to the rates in England and Northern Ireland, was caused by worries expressed by the physicians regarding the reliability and quality of the generic drugs in the market (McGavock, 1997).

A study conducted by Mott and Cline in the USA utilised a database containing information on 6380 prescription orders for analysis. The researcher used this data to examine the influences of the prescriber, pharmacist, insurance, patient, and drug variables on whether or not generic drug use and generic substitution was permitted when writing prescriptions. More than 60% of the prescription orders provided an opportunity for generic drug use, and more than 80% of them substituted by pharmacists and dispensed generic medicines. Physicians and pharmacists play important roles in increasing the use of generic drugs and generic substitution. Generally, private insurance reduces the use of generic medicines and generic substitution. Also, prescriptions for chronic diseases have a negative correlation with generic medicine use and generic substitution. Patient characteristics also play an