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IRAQ PRIVATE SECTOR GROWTH AND EMPLOYMENT GENERATION

April 17, 2007

Pharmaceutical and Medical Products in Iraq

IZDIHAR
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This publication was produced for review by the United States Agency for International Development. It was prepared by the joint venture partnership of The Louis Berger Group / The Services Group under Contract # 267-C-00-04-00435-00

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The IRAQ IZDIHAR project is funded by the United States Agency for International Development (USAID) and implemented by the joint venture partnership of:

THE Louis Berger Group, INC.
Engineers Planners Scientists Economists

TSG THE SERVICES GROUP
International Economic Consulting

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1.0 EXECUTIVE SUMMARY

1.1 Introduction

The aim of the study is to analyse the pharmaceutical and medical products sector to enable the development of recommendations for private sector business investment strategies and programmes. This has been conducted, within the constraints of the current circumstances, to analyse the demand side of the sector, the nature of procurement and distribution within Iraq, and where available, examine current supply side, public and private, and competitive interests.

The report looks at the supply of products within these sectors, and then examines the formal procurement and distribution system, and then the current position.

1.2 Background

Iraq has been through a turbulent three decades, in which it has been involved in three major conflicts, namely the Iraq-Iran war, the invasion and subsequent defeat and retreat from Kuwait, and finally the invasion of Iraq itself with the removal of the Saddam regime. This was immediately followed by the CPA administration, followed by the Interim Governing Council and then a duly elected Iraqi Government. In the period between 1991 and 2003 UN sanctions were imposed on the country.

Prior to the Iraq-Iran war it was generally recognised that Iraq had an effective and well managed public health system. Pharmaceutical products and medical services were generally heavily subsidised and most of the population received adequate health care. It is noted however that there were then, as now, a significant variance between those services in rural, remote areas, and the urban population.

The period of sanctions had a distinctive effect on the healthcare sector, and, as it pertains to this report, pharmaceutical spending. During this time, particularly prior to 1996, when the regime signed a Memorandum of Understanding (MoU) with the UN, the regime spent (UN estimate) USD 40-50 million, down from nearly USD 200 million previously. The health of the nation suffered commensurately, with rises in infectious and communicable diseases, infant, perinatal and maternal mortality, and a significant decrease in average life expectancy. In addition with restrictive diets effectively imposed by the regime in response to sanctions, dietary complications dramatically increased the susceptibility, through malnutrition, of the population to nutritional deficiencies and consequential susceptibility to infection.

Following the second Gulf War with the war damage on power generation and collateral damage to water treatment plants, health further degenerated with increases in water born diseases, particularly again affecting the young and the elderly.

It is generally believed that the regime manipulated the lack of pharmaceuticals and declining healthcare system to gain sympathy for its, understandable, position against sanctions. However the impact was significant, and over that period there were large increases in the incidence of conditions such as kwashiorkor, marasmus and other nutritional disorders.

Common childhood diseases increased significantly with mortality from measles, whooping cough (pertussis) and mumps. With lack of preventive active vector control programmes, acute forms of malaria (particularly in the Northern Governorates) and visceral leishmaniasis increased, and indeed geographically spread. The incidence of tuberculosis significantly rose.

Water born disease also rose, particularly the incidence of cholera, diphtheria and typhoid. This was also due to the requirement of the UN resolution to remove weapons of mass destruction (WMD) that severely restricted the supply of chlorine to the water treatment plants.

1.3 Pharmaceutical Sector

Pharmaceuticals in Iraq are supplied either domestically or through imports. Prior to 2002 there was a single (state owned) pharmaceutical production company in Iraq, variously estimated at supplying 20-30% of the basic needs of the country. The balance was imported. In 2002 the company was split, and respectively two companies, Samarra and Nineveh were ordained. It is important to note that the purchase and distribution of all pharmaceutical and medical products prior to 1994 were in public control, as discussed below. Subsequent to that year, relaxation of controls of private industry allowed the development of private pharmacy outlets with up to an estimated 700 being established. However, the procurement of pharmaceuticals (and medical products) for the main lies wholly within the remit of Kimadia, the operational arm of the Ministry of Health (MoH). This is effectively for the private as well as the public sector, thus the sector is characterised by:

- command economy
- an effective monopsony
- centralised purchasing and distribution
- pricing controls and subsidisation
- very low current consumption

Domestic manufacture has been variously estimated, but currently probably accounts for 50% by volume of pharmaceutical products. In 1989 this estimate was some 30%, and estimates vary but indicate that during sanctions it may have reached in excess of 60%. The report describes the imports into Iraq, from a historical perspective, with longitudinal data encompassing twenty-five years, with sources. The section concludes that the current market value is probably worth some USD 200 million, with a potential to grow to some USD 250 million by 2010. The market is compared with similar regional markets. This compares with a value ascribed in 1989 of some USD 360 million across the pharmaceutical and medical products sector.

Domestic private manufacture comprise some 15 small licensed operations, in addition there are a variety of unlicensed manufacturers who have taken advantage of the current political and security situation to establish illegal operations. All of these produce generic products from imported active ingredients and excipients, mainly syrups, creams and ointments and suppositories. There is domestic manufacture of parenteral and i.v. fluids in the state sector, in addition a phial manufacturing facility was built, but is understood to be non-operational.

Recent developments include investment into an antibiotic plant in the state sector.

1.4 Medical Products Sector

This section defines and describes the medical products sector, which includes such items as orthopaedic devices, hospital consumables, and items such as X-ray tubes. All of these items, apart from small numbers of orthopaedic aids (wheelchairs, walking sticks, crutches) are imported through Kimadia. The estimated current value of the market is USD 63 million with a forecast value in 2008 of USD 80 million. Recent developments have included the investment for a syringe manufacturing facility funded by Iran, and reportedly an investment into the phial production facility. A regional comparison is included.

1.5 Ministry of Health, Public and Private Procurement

Procurement in Iraq, as described previously is managed entirely through an operational arm of the Ministry of Health known as 'Kimadia'. All public procurement is through public tender announced through Kimadia's web site – www.kim-moh.net. Under the rules of tendering the supplier has to be authorised by the Ministry to tender, one of the aspects of which is the notarisation of a letter appointing the supplier sole agent, or manufacturer for a specific product (or set of products, etc.). This is then reviewed by the MoH, a supplier is selected and the tender awarded. By inspection of the rules the system is very open to rent-seeking, and difficult to penetrate as a new supplier, given the nature of the pharmaceutical business, is restricted to products not covered by previous agreements. These rules are available on the web site cited.

There is no pharmaceutical promotion or marketing in Iraq.

Subsequent to procurement by the MoH the products are then distributed though Kimadia's own chain of warehouses and distribution centres. Allocation decisions are made by the Ministry, and there are often complaints that these decisions are made unfairly, that the Ministry creates shortages, and that pharmaceuticals particularly can arrive at the point of distribution past their sell by date. The Ministry also supplies the retail pharmacists, who then sell on.

In the private sector sourcing has not been able to be quantified, however, it is known that some purchases are imported but a significant proportion comes from the Ministry, through Kimadia established mechanisms. This significantly distorts pricing, with the MoH effectively subsidising costs to the private sector, thus reinforcing profits in the sector.

The Ministry is responsible for licensing and regulating manufacturing facilities, and retail pharmacists, which role it legally enforces through a variety of inspection teams. In the current situation the regulatory enforcement regime has failed and drugs are freely available in the marketplace, either having been sold there illegally by Kimadia/MoH, sourced from illicit imports, or from goods looted from the Kimadia warehouses.

1.6 Private Sector Investment

In conclusion there are a number of specific routes to entering the pharmaceutical sector in Iraq: these can be briefly summarised as:

- An external supplier
- An importer and distributor
- A low value manufacturer

– A high value manufacturer

Each of these may be evaluated separately; however, within the current system each of these has major constraints:

External supplier: A major element is competition with current embedded contractors for major supplies; a new entrant has to establish credentials as being the sole supplier (agent) for tendered products or materials, or as a manufacturer gain acceptance for the company's product (s)'s through a lengthy process, thus suggesting only those that supply wholly new products or supplies gain access to the domestic market.

Private importer/distributor: Current conditions require complicity with pharmaceutical distributorships; most of these are already in the hands of a select few wholesalers/distributors, requirement for licensing, opportunity for volume/margins low as main pricing in the control of the MoH/Kimadia.

Low value manufacturer: Capital cost of establishing a business, real main competitors are the low value (unlicensed/illegal) manufacturers, and then there is the challenge of establishing a distribution chain. Opportunities for non-domestic players are small if not negligible.

High value manufacturer: Capital cost of establishing, and maintaining plant, currently small domestic market, but this might be an option for the future.

In the short term, until the conditions set out in the recommendations are fulfilled, there are few opportunities for external investors, except where these are government backed. In the long-term, with the additional support of the government funded research institutes there is a good prospective for the pharmaceutical industry in Iraq, albeit initially at the domestic level.

An initial approach is potentially for a long-term investment at the SME level. It is suggested this would have to be a joint venture with a current manufacturer, whether, for cash and technology, with the manufacturer coming from the currently private, or a re-structured public sector.

1.7 SWOT

Strengths

- Active manufacturing – public, private and illegal
- Strong market demand
- Active government procurement
- Entrepreneurial culture developing

Weaknesses

- Monopsony purchases
- Unregulated market sales (secondary/black/grey), of illegal imports, inadequately controlled domestic production, ineffective and sub-standard products
- Lack of regulatory enforcement of standards for GMP,GLP, pharmaceutical sales, product sourcing, patent protection etc

- Bureaucratic
- Price controls
- Differential pricing regimen
- Economic uncertainty
- Low real per capita consumption compared to OECD market
- Govt contracts unpredictable (only tendered when money available)
- Unreliable payment system
- Health care system in disarray
- Loss of healthcare professionals
- Shortage of qualified technical staff
- Sectarian issues

Opportunities

- Potential privatisation programme(s)
- As public sector finances improve, per capita expenditure will grow
- Major import substitution opportunity
- Opportunity to licence in products
- Opportunity to buy into local producers with technology transfer package
- Opportunity in niche sectors, e.g., phials, sterile products etc
- Undervalued assets
- Unused facilities
- Joint ventures
- Specialist Manufacture – Long-term

Threats

- Security situation (personnel)
- Rent seeking (bribery, corruption, protection rackets etc)
- Security situation (property) threat of theft, looting, vandalism
- Lack of effective banking and cash management systems

1.8 Recommendations

This study by its nature was primarily a desk study with interviews being carried out whenever possible due to the means and circumstances under which was conducted, with restrictions on access to the factories, both public and private, and to the Ministry of Health. This preliminary study should be revised when conditions permit access to actual performance statistics, the Ministry of Health and its operating subsidiaries.

It is apparent that the industry sectors considered are open to investment opportunity, however, the system constraints, explored in the body of the document, requires structural adjustment. Therefore, subsequent to the prime recommendation, the main recommendations of this report are of a policy and regulatory nature.

Formal definition of the nature, business and manufacturing assets of each of the state enterprises must be established.

The rules, regulations, by-laws by which a (private) entity may make an offer to supply goods and, or, services to the state sector should be revised.

The appropriate provision under extant company law for a company to freely compete in the new liberal market economy without prejudice or favour (to include the provisions that will be made under free market legislation) should be able to be applied under the Kimadia procurement system.

The proper registration of all businesses with appropriate deterrents and sanctions should be in effect.

The Ministry of Health should carry out, and is enabled to carry out, its legal responsibility to ensure GMP and GLP, in each and every instance.

The Ministry of Health, and in particular, its' operating subsidiary known as 'Kimadia' should be thoroughly restructured, to enable transparency in its dealings, and that its functions be restricted.

The system of licensing, approvals, and registration with its inherent opportunity for rent seeking should be reviewed and appropriate deterrent and sanction be introduced.

There is a potential for a long-term investment at the SME level. It is suggested this would have to be joint ventures with a current operator, for cash and technology.

It is apparent from this study, and many others cited, that there are significant opportunities for investment in the Iraq pharmaceutical and medical products sectors.

However, as a result of many decades of operating under a command economy, and the last several decades of war, sanctions and internal strife a variety of measures need to be undertaken before a liberal market economy can exist in this sector.

It is understood that a government which wishes to create a public health system, underwritten by the state must have control of its own purchases; however there exist constraints within the system, as outlined in the document, which allow opportunism and rent seeking.

This report was written with limited capacity to engage the Ministries and the domestic manufacturing sites, so there are inherent frailties within it. The recommendations are therefore prefaced with the need to conduct further research as conditions improve and circumstances permit.

The pre-requisite for investment in the state sector is the creation of appropriate privatisation and restructuring mechanisms. For a variety of reasons the Government of Iraq and its agencies may not wish to privatise in one move, however, structure must be developed that allow the opportunity for private-public partnership programmes (PPP), private funding initiatives (PFI) or similar constructs. The following recommendations outline some of the preliminary steps to be taken.

It is essential that reform of the state enterprises be undertaken to remove some of the gross inefficiencies that occur within the state sector, cross subsidisation, false pricing, embedded work practices, and in the pharmaceutical sector, the re-establishment of the compliance (GMP, GLP etc) inspection teams from the MoH in both the public and private sector.

In addition the non-transparent price subsidisation of goods, through the MoH to both the public and private sector has to be reformed.

1.9 Kimadia Improvement and Enhancement Programme

There is a US Government funded initiative about to be launched that is to address many of the issues raised in this document, and make appropriate recommendations for the reform of the Kimadia organisation, and ultimately to their implementation.

2.0 INTRODUCTION

The aim of the study is to analyse the pharmaceutical and medical products sector to provide the basis for the development of recommendations for business development and investment strategies and programmes.

The report looks at the supply of products within these sectors, and then examines the formal procurement and distribution system, and then the current position.

Iraq has been, to all intents and purposes, a command economy for many decades and the pharmaceutical and medical products sector reflect this. Domestic manufacture of pharmaceuticals was until approximately 1994 entirely within the remit of single monolithic state company – The State Company for Drugs and Medical Supplies. Following that year ordinance was passed allowing the development of a private manufacturing sector, which, though small, still exists. Procurement within the sector however remains within a central purchasing and distribution organisation – Kimadia – a wholly owned operating company of the Ministry of Health. This organisation also supplies the private sector wherein the current situation the regulatory enforcement regime has failed and drugs are freely available in the marketplace, either having been sold there illegally by Kimadia/MoH, sourced from illicit imports, or from goods looted from the Kimadia warehouses, as well as the hospital and clinic outlets. Prior to the current period, however, corruption, as well as state supported mechanisms also enabled supply through Kimadia to the private sector.

As is well known Iraq has suffered several decades of armed conflict, external and internal. In the 1980's the regime of Saddam Hussein prosecuted a fruitless war with Iran over the Al Faw peninsula which severely damaged the economy, and though indebting the country was supported by the West. In 1990 Iraq invaded Kuwait and subsequently in 1991 was evicted with considerable long-term implications. The first of these was the destruction of a significant element of the military, the second was the explicit call upon the Iraqi people to remove the regime, which having been responded to by the Shia of the south and the Kurds in the north-east was not supported by the Allies. These risings were then brutally suppressed, to which the allies responded by creating the no-fly zones in the north and south, and an effective Kurdish safe enclave in the north-east. The third effect was the imposition of economic sanctions with the overt aim of destroying Iraq as an international threat with the destruction of weapons of mass destruction, and the covert, or implicit, aim of removing the Saddam regime. These sanctions caused the regime to respond in a manner that economically destroyed the country, created a humanitarian disaster that is reflected in the state of the healthcare industry today.

Since the occupation the country has, and continues to experience, severe levels of criminal activity, violence, sectarian conflict bordering on civil war. In addition during the period of sanctions and subsequently, there has been no investment in the state owned enterprises, including the pharmaceutical manufacturing sector; this includes a significant lack of access to materials for routine maintenance, and spare parts as required. Thus most factories are in poor state of repair. It has not been possible to survey the domestic manufacturing facilities in the preparation of this report, however, with the depredations created through the sanctions regimen, lack of facility for full maintenance, it is understood that they are not functioning at capacity, and possibly, or probably would not meet GMP standards[1]. The private sector companies will also suffer from the same problems, though the 'illegal' (unlicensed opportunist manufacturers) facilities would never have intended to.

[1] Personal communication; February 2007.

3.0 BACKGROUND TO THE IRAQI PHARMACEUTICAL AND MEDICAL PRODUCTS SECTOR

3.1 Introduction

The following paragraphs give a basic background to the current medical situation in Iraq, with some data on morbidity and mortality statistics. Because of the current security, and political status within the country some of these data are old but compared with more recent data where this is available. It is recognised by the author that some of the sources are not reliable, per *se*, and many of the considered citations themselves recognise that quoted figures are estimates or are extrapolations based on previous census or survey figures. However they are quoted here to provide a view of the health status of the country to potential investors in the pharmaceutical and medical products market.

3.2 Background on Iraq

Prior to the last two decades Iraqi healthcare was generally recognised as being amongst the best in the region. However, a series of key events over these decades have effectively destroyed the effective provision of healthcare. From 1980-88 Saddam Hussein[2] fought an inconclusive but very costly war with Iran, and then in 1990 invaded Kuwait, followed by the Gulf War of 1991.

Following the liberation of Kuwait, sanctions were imposed by United Nations Security Council Resolution 687 with the overt purpose of encouraging Iraq to disarm its weapons of mass destruction and covertly to encourage the fall of the Saddam regime. The effects of these were economically disastrous, with the collapse of much of the country's infrastructure. Significantly the effects were enormous on the health care system, with estimates of deaths resulting from the effects of sanctions running to a million. UNICEF estimated the number of child deaths at 500,000. These deaths were as a result of lack of medical supplies, clean water and malnutrition.

Because of the criticism, which rapidly mounted, of the humanitarian effects of the sanctions a series of UN Resolutions were passed creating the Oil for Food program, the first of these in 1991, however, the Government of Iraq (GoI) refused to acknowledge or comply until May 1996 when it signed a Memorandum of Understanding (MoU) allowing the Resolutions to take effect. The programme started in October 1997 with food deliveries in 1998.

Following the 2003 invasion of Iraq the sanctions regime was lifted.

[2] CIA the World Factbook 2007; www.cia.gov/cia/publications/factbook/print/iz.html

3.3 Healthcare Sector

Iraq, as a country with a nominal population of approximately 27 million, an estimated GDP per capita of USD1,900 per capita (at PPP), but with potentially vast oil wealth should be in a position to provide a level of general healthcare commensurate with that of any of the richer gulf states. However, the general state of health in Iraq has been substantially reduced owing to the wars of 1991 and 2003, the period of sanctions following the retreat from Kuwait, and the mismanagement of the economy prior to and during that period. Following the removal of the Saddam regime significant looting and pillaging of healthcare facilities, the theft and destruction of equipment, medical supplies took place with enormous detrimental effect to the sector and healthcare in general.

There are significant differences between the urban and rural medical service available to the respective populations. This has been exacerbated with the significant loss of healthcare professionals from the country, both on the medical professional – doctors, nurses, and the pharmacy side, from the specialist clinics the governorate general and specialist hospitals.

The following paragraphs give, from a variety of (referenced) sources basic population statistics. It should be noted the significant difference between the 2006 figures given by the CIA Factbook and those offered by UNICEF and the WHO. Overall data offered by the former demonstrate a significantly healthier and longer lived population than the latter.

3.3.1 Socioeconomic Indicators

Table 3.3.1 gives basic socio economic indicators for the period prior to sanctions in Iraq 1988-89[3] and 2002/3[7].

Table 3.3.1 Socioeconomic Indicators 1988/9 and 2000-2003

Indicator	1988/9	2000 – 2003
GNP per capita (USD)	2,800	
% female literacy	85%	43% (2000)
% population with health care	93%	98% (2001)
% population with safe water	90%	85% (2002)[4]
% pregnant women with maternity care	78%	67% (2002)
% pregnant women with trained attendant at delivery	86%	55% (2003)

3.3.2 Mortality and Morbidity

Communicable diseases are a major cause of mortality and morbidity in Iraq[5,6]. Three of the major killers are acute lower respiratory infections (ALRI), diarrhoeal diseases and measles. ALRI and diarrhoea alone account for 70% of deaths in children under 5 years of

[3] The Health Conditions of the Population in Iraq since the Gulf Crisis. World Health Organization, March 1996

[4] It is noted that this figure is considered by domestic authorities to be too high; noting that the southern region was very badly affected, and Baghdad itself was badly supplied. It is possible, but uncorroborated, that the MoH, and or other parties, exaggerated these figures for political effect.

[5] WHO Communicable Disease Profile for Iraq. Updated 19 March 2003. WHO Geneva.

[6] Health in Iraq. The Current Situation, Our Vision for the Future and Areas of Work. Ala'din Alwan, Minister of Health. Ministry of Health. Second Edition, December 2004.

age. Typhoid increased threefold between 1996 and 2000, measles increased sharply in 1997, and again in 2004. Hepatitis E outbreaks are increasingly reported.

The increase in these diseases has been mainly a result of the sanctions regime introduced in the 1990s, and ironically the requirement to destroy weapons of mass destruction. These caused a lack of medical supplies, reduced[4] access to clean water – one of the consequences of banning the manufacture of chlorine – and malnutrition. And all of these exacerbate problems created by the effects of the various wars and internal suppression, internally displaced persons, refugees, slums, overcrowding, the destruction of sewage plants, restriction in the electricity supply etc. Cholera became endemic after 1991, with outbreaks in 1998 and 2002 and diphtheria presenting potential problems.

Vaccination programmes have since been put in place, with the MoH/USAID claiming 98% of children now vaccinated with MMR and 97% of children vaccinated against polio. However other vaccine-preventable diseases such as pertussis (whooping cough) and diphtheria also continue to occur throughout the country. Pertussis incidence remains high and appears to be increasing.

Other significant infectious disease on the increase in this period are tuberculosis (TB) as a result of overcrowding and following the Gulf War malarial outbreaks, although the incidence has declined with the institution of vector control programmes.

Visceral leishmaniasis has increased in central Iraq and the greater Baghdad area as a result of increased density of sandfly vectors, movement of people and deterioration in the health status of the population.

3.3.2.1 Morbidity and Mortality Statistics

3.3.2.1.1 *Basic Health Indicators*

Table 3.3.2.1.1 gives the basic health indicators for the Iraqi population prior to sanctions 1988/9 and post occupation 2002/3[7,8].

Table 3.3.2.1.1 Health Indicators 1988/9

Indicator	1970	1989/9(7)	1990[9]	2000	2003(7)	2005	2006(2)
Population (millions)						28.807	26.78
65+ Male							0.38
65+ Female							0.42
15-64 Male							7.78
15-64 Female							7.6
Pop. Under 18						13.759	
Under 14 male							5.39
Under 14 female							5.23
Pop. Under 5						4.322	
Median age							19.7

[7] WHO Country Office in Iraq. www.emro.who.int/iraq

[8] With a variety of reporters there are significant differences in reported incidences; notably between the MoH, and various international organisations, sampling techniques etc, there are apparent significant differences. This section of the report is designed to give an overall picture of the status of the population at the given dates, not to represent accurately the given state.

[9] UNICEF: www.unicef.org/infobycountry/iraq_statistics.html

Table 3.3.2.1.1 Health Indicators 1988/9 (continued)

Indicator	1970	1989/9(7)	1990[10]	2000	2003(7)	2005	2006(2)
Pop growth rate							2.66%
GNI/capita (USD)						2,170	
Literacy (200							
No of births ('000s)						978	
Birth rate per 1,000 population		43			30		32
No of under 5 deaths						122	
Crude death rate per 1,000 population	12	8.0	8		8	9	5.4
Crude birth rate	46		39			34	
Infant mortality, per 1,000 live births[11]		52	40		107	102	49
Under 5 mortality per 1,000 live births	127	94	50		130	125	
Neonatal mortality				63			
Maternal mortality per 100,000 live births		160			29.4		
Low birth weight (below 2.5 kg)		5%			6%	15%	
Life expectancy (comb)	56	66 years	63	63.2		60	69
Life expectancy (m)				61.7			67.8
Life expectancy (f)				64.7			70.3

3.3.2.1.2 *Infant and Maternal Mortality and Morbidity*

Table's 3.3.2.1.2 (a), (b) and (c) demonstrate the effects of malnutrition on childhood mortality the consequential incidence of nutrition related conditions and neonatal birth weight. These show that immediately prior to the war resulting from the invasion of Kuwait these were relatively low and subsequently showed a large increase immediately in 1991 with this continuing increase to the limits of this data in 1995.

Table 3.3.2.1.2 (a) Monthly average cases of malnutrition in children[12] under 5 admitted to hospital[13]

Year	Kwashiorkor[14]		Marasmus[15]		Other malnutrition	
	No	Per 100,000	No	Per 100,000	No	Per 100,000
1990	41	2	433	14	8,063	269
1991	1,066	34	8,015	258	78,990	2,542
1992	1,145	36	9,289	269	93,610	2,511
1993	1,261	38	11,612	349	102,971	2,989
1994	1,748	51	16,025	465	131,349	3,613
1995[12]	2,237		20,549			

[10] UNICEF: www.unicef.org/infobycountry/iraq_statistics.html

[11] Defined as death within the first year of live birth. There is discussion concerning reporting of live births, e.g., seriously under weight births, or undersized babies that die after birth, though on strict definition were 'alive' i.e., showing signs of muscle movement, gasping etc in some countries are not reported. On a strict definition for 1997 in the US a comparative figure is 7.1 per 1,000 live births.

[12] The Status of Children and Women in Iraq: A Situation Report. UNICEF September 1995 cited Iraq Action Coalition. 1995 figure MoH figure cited Jan-July

[13] It is noted that apparent differences in total child population are caused by different reporting methodologies used by the different reporting authorities

[14] Caused by protein deficiency, early signs are apathy, lethargy, lack of stamina, loss of muscle mass, swelling, abnormal hair (sparse, thin) abnormal skin. Disabled immune system leads to susceptibility to multifarious infection.

[15] Wasting away, also called cachexia, caused by protein and calorie deficiency

Table 3.3.2.1.2 (b) Reported mortality in children less than 5 years old from selected causes (less 3 northern governorates)[16]

Year	No	100,000
1990	8,903	257
1991	27,473	884
1992	46,933	1,460
1993	49,762	1,495
1994	52,905	1,536

Table 3.3.2.1.2 (c) Percentage of low birth weight to total birth weight

Year	% LBW
1990	4.5
1991	10.8
1992	17.6
1993	19.7
1994	21.1

The average perinatal mortality rate for Iraq[17] was estimated to be 28 per 1,000 live births during the period 1989-90, similar to other countries in the region at the time. The average rose in the period 1999-199 to 107 per 1,000. The causes for this increase are low birth weight, perinatal infections, and birth asphyxia due to foetal hypoxia. Many of these could be prevented through management of communicable diseases, good care at birth by qualified attendants, tetanus toxoid use etc.

3.3.2.1.3 *Disease Incidence*

The following paragraphs and tables give the incidence of specific diseases in the period 1989 to 1994, and there where available the incidence of that disease since 2000. The diseases are namely:

- Malaria
- Cholera
- Typhoid
- Leishmaniasis
- Tetanus
- Poliomyelitis
- Diphtheria
- Pertussis

Malaria

Table 3.3.2.1.3 (a)[18] shows the incidence of malaria from 1989 to 1994. This clearly demonstrates the increase in incidence following the Kuwait war. In addition it demonstrates the significant difference between the northern states (the three governorates) and the rest of the country. This situation is still the case, however morbidity from malaria has significantly decreased with figures for overall incidence in 2003 being 347 and in 2005, 47[19].

[16] Ministry of Health, Iraq cited WHO (5) op cit. Assumed all subsequent tables to be less the Northern Governorates.
[17] Nasheit NA. Journal of Maternal-Fetal and Neonatal Medicine. **13** (1) 64-67 (2003).
[18] All the tables in this section refer to the 15 governorates and the 3 'northern governorates
[19] WHO Country office, 1996 and 1997, www.emro.who.int/emrinfo/index.asp?Ctry-Irq

Table 3.3.2.1.3 (a) Malaria incidence

Year	Malaria Incidence rate (15 governorates)		Malaria Incidence rate (3 Northern governorates)	
	No	Per 100,000	No	Per 100,000
1989	1,510	10.4	1,918	87.2
1990	1,761	11.7	2,163	95
1991	4,025	25.9	1,087	46.1
1992	5,535	34.4	12,916	530.2
1993	4,589	27.6	36,490	1,466.0
1994	22,169	128.7	67,462	2,585.2

Enteric infections

Table 3.3.2.1.3 (b) gives the incidence of enteric infections. Again it may be seen that during the period of sanctions the incidence increased, however subsequent reports (19) shows a significant decline in the incidence of cholera, to 517 in 2003 and 44 in 2005. This reference does not cite incidence for typhoid, however a similar picture would be expected.

Table 3.3.2.1.3 (b) Incidence of water born diseases

Year	Incidence of cholera		Incidence of typhoid[20]	
	No	Per 100,000	No	Per 100,000
1989	0	0	1,686	11.6
1990	0	0	1,691	11.3
1991	1,217	7.8	17,524	112.8
1992	976	6.1	19,276	119.9
1993	825	5	18,724	112.5
1994	1,344	7.8	24,474	142.1

Vector born disease

Table 3.3.2.1.3 (c) offers the incidence of leishmaniasis[21] (kala azar) again showing significant increase in incidence through the period of sanctions. Thee sources do not giver overall levels of incidence however, the literature reports the use of management programmes, e.g., fly eradication that have significantly reduced the total incidence in specific provinces, e.g. Dhi Qar[22].

Table 3.3.2.1.3 (c) Leishmaniasis incidence in Iraq

Year	Leishmaniasis incidence	
	No	Per 100,000
1989	2,159	14.9
1990	2,375	15.8
1991	11,946	76.9
1992	12,645	76.6
1993	11,155	67.0
1994	9,348	54.3

[20] Typhoid incidence differs from cited figures in UNICEF Sept 1995 Op cit. where: 1989, 1,812; 1990, 2,240; 1991, 17,524; 1992, 19, 276, 1993, 22,688; 1994, 24,436.

[21] A protozoan (Leishmania) infection of the skin, mucosal membranes or viscera transmitted through the bite of the sand fly.

[22] Jassim et al. Visceral leishmaniasis control in Thi Qar Governorate, Iraq 2003. WHO Eastern Mediterranean Health Journal **12** (Suppl. 2)

Infectious diseases

Table 3.3.2.1.3 (d) shows the incidence of tetanus, poliomyelitis ('polio'), diphtheria and pertussis (whooping cough) in children and infants during the initial sanction period in Iraq. Tetanus incidence was reported at 0 in 2003, and up slightly to 6 in 2005. No cases of polio were reported in 2001 or 2005. Incidence of diphtheria declined from 16 in 2003 to 6 in 2005, pertussis incidence is not reported.

Table 3.3.2.1.3 (d) Incidence of infectious diseases

Year	Incidence of tetanus (< 15 years old)		Incidence of poliomyelitis (< 15 years old)	
	No	Per 100,000	No	Per 100,000
1989	30	0.21	8	0.12
1990	80	0.53	38	0.57
1991	933	6.01	153	2.22
1992	98	0.62	113	1.58
1993	64	0.38	72	0.97
1994	38	0.22	56	0.73

Year	Incidence of diphtheria (< 5 years old)		Incidence of pertussis (< 5 years old)	
	No	Per 100,000	No	Per 100,000
1989	71	2.4	342	11.8
1990	144	4.8	397	13.3
1991	511	16.4	1,537	49.5
1992	369	11.4	1,601	49.8
1993	240	7.2	767	32.1
1994	132	3.6	534	15.5

Year	Incidence of measles (< 5 years old)		Incidence of meningitis(< 5 years old)	
	No	Per 100,000	No	Per 100,000
1989	5049	174.1	2,263	15.6
1990	6,486	216.1	1,561	10.4
1991	11,358	366.6	5,792	37.3
1992	20,160	627	4,534	28.2
1993	16,258	468.5	3,789	22.8
1994	10,657	369.4	3,074	17.8

With widespread immunisation programmes, the reported indicator for measles in 2003 was 433 with a rise to 604 in 2005. A widespread immunisation programme should help to reduce the total number of cases and should eradicate any associated mortality. Meningitis showed an increase to 135 in 2003 with a reduction to 48 in 2005.

Other diseases and infections with decided increases over the period of sanction followed by the period subsequently include tuberculosis becoming endemic (3,381 in 2005), and significantly, an increase in the incidence of hospital acquired infections.

4.0 PHARMACEUTICAL SECTOR

4.1 Introduction and Definition

As noted this report covers pharmaceuticals, pharmaceutical products, certain medical consumables, medical products and devices. This section, for simplicity takes account of those products listed under the Harmonisation Code Chapter 30 – Pharmaceutical Products[23] (Ch 30 is appended in Appendix A see footnote). An abbreviated schedule is given in table 4.1. This also includes, as well as prescription and over the counter products (OTC).

Table 4.1 Abbreviated selected HS headings of Section 6 Chapter 30 'Pharmaceutical Products'

PRODUCT	HS Code
Antisera	300210
Vaccines for human use	300220
Containing penicillin (bulk)	300310
Containing antibiotics (bulk)	300320
Hormones/steroids (bulk)	300339
Containing 2 or more ingredients (bulk)	300390
Penicillin or derivatives	300410
Antibiotics	300420
Insulin	300431
Corticosteroids	300432
Hormones/steroids	300439
Alkaloids	300440
Provitamins/vitamins	300450
Containing 2 or more ingredients	300490
Adhesive dressings	300510
Wadding, gauze, bandages	300590
Surgical cat gut etc.	300610
Reagents for determining blood groups	300620
Opacifying material (for X rays)	300630
Dental cement etc	300640
First aid boxes & kits	300650
Chemical contraceptives	300660
Gel	300670
Waste pharmaceuticals	300680

4.2 Pharmaceutical Market - Characteristics

The pharmaceutical market shares key characteristics of the economy; namely that it is a command, or centralised economy, with the significant elements that that implies. In addition the pharmaceutical market, as formally established, is effectively a monopsony, with probably in excess of 90% of pharmaceutical purchases managed through the Ministry of Health (MoH). The MoH issues public tenders, is responsible for the purchase, and through an operational subsidiary (known as Kimadia), the distribution of

[23] Embodied in the US 'Harmonized Tariff Schedule of the United States (2006) – Supplement 1 (Rev 2).

pharmaceutical (and medical product) supplies to the public (or state) hospitals and clinics which constitute the greater part of the Iraqi healthcare system.

During the period of sanctions, especially prior to the 1996 signing of the Memorandum of Understanding, supplies were very restricted into the MoH system. Throughout this period it is understood that the regime manipulated the supply of drugs and availability of healthcare for political reasons.

The market is characterised by:

- command economy
- effective monopsony
- centralised purchasing, distribution
- pricing controls
- very low consumption

4.3 Sources of Supply

4.3.1 Introduction

Until 1994 the supply of medicine generally was dominated by the public and semi-public sector with about 90% of drugs made available through the public budget system. Distribution, and marketing, again by law, was through the Kimadia (see below) system. From 1994 the government facilitated private enterprise and about 700 new pharmacies were opened. In 2003 private enterprise was estimated to supply some 25% of all pharmaceuticals.

In 1989 MoH reported spending USD 360 million on imports of pharmaceuticals, vaccines, medical appliances and disposable supplies.

By 1990 the supply of drugs started to be rationed, 1990-97 WHO estimated that the government distributed USD40-50 million per annum, some 10-15% of estimated needs.

Thus supply can be split into the two key areas of domestic manufacture and imports, each of which is discussed below.

4.3.2 Domestic Manufacture

Domestic manufacture probably accounts for 40-50% of current domestic demand, though in 2003 this was reported as up to 60% previously and it is noted that all specialist products are imported. In 1989 the estimate was 30% contribution.

The manufacturing capacity is split between the public sector, and the private sector.

4.3.2.1 Public Sector

The manufacturing facilities in the public sector comprise the following production facilities[24]:

- Abu Ghurayb Veterinary Production

[24] Sources include: Chemicals and Allied Products: Iraq Pharmaceutical Sector 2004. Coalition Forces 2004.

- Amiriyah Serum and Vaccine Institute
- Arab Company for Antibiotics Industry
- Baghdad Factory for IV Production and Medical gases
- Baghdad South Saline Production
- Dawrah Vaccine Production
- State Company for Drug industries – Ninewa (Mosul)
- State Company for Drug Industries – Samarra

Prior to 2002 the state or public sector comprised of the single company 'the State Company for Drugs and Medical Supplies – Ninewa & Samarra' which acted as a state holding operation for the above (less Veterinary Production unit). In that year the Nineveh operation was split off and created as a single corporate entity.

Samarra now comprises: the eponymously sited headquarters and manufacturing operation, disposable syringe factory in Baghdad and the glass vials factory.

A valuation by CPA in 2003 suggested a market price for the entirety of between USD 10 and 20 million.

Each entity is described in the paragraphs below, and then the state entities are described last with product lists.

4.3.2.1.1 *Abu Ghurayb Veterinary Production*

Produces veterinary supplies.

Products:
– Cholera Vaccine
– Typhoid Vaccine
– Tetanus Anti-serum
– Foot and Mouth Disease Vaccine
– Other Parasitic, Bacterial, Viral Vaccines

4.3.2.1.2 *Amiriyah Serum and Vaccine Institute*

Primary Serum and Vaccine Institute.

Products:
– Cholera Vaccine
– Typhoid Vaccine
– Snake anti-venom

In addition acting as a store for UNICEF, stock (2004) included:
– Polio
– DPT
– Rubella
– MMR
– Tetanus
– Hepatitis B
– Rabies
– Bacille Calmette-Guerin (BCG)

4.3.2.1.3 *Arab Company for Antibiotics Industry*

Produces antibiotics in vials, tablets, capsules, syrups, ointments and ampoules.

Designed in 1984, built 1989-2001.

Design capacity:
– 300 million antibiotic capsule
– 28 million injection vials
– 18 million bottles of suspensions

Production:

Began producing Amoxicillin and Ampicillin in May 2002.

Production June 2002:
– 292,500 bottles of Amoxicillin
– 5.76 million capsules of Ampicillin

In February 2007 it was announced that the Ministry of Finance was to borrow over ID 9 billion[25] to purchase outstanding stock in the company.

4.3.2.1.4 *Baghdad Factory for IV Solutions & Medical Gases Production*

Produces medical gases. It is the largest producer of medical gases in Iraq.
- Nitrous Oxide
- Oxygen
- IV Solutions

Facilities include a glass workshop.
- Supplies ampoules to outside customers
- Capable of making medically unique items

In 2003 it was reported that the IV factory was damaged beyond operation, with an estimated charge of USD 2 million for restoration. In addition it is believed that the glass ampoule (or vial) line is inoperative.

4.3.2.1.5 *Baghdad South Saline Production*

4.3.2.1.6 *Dawrah Foot and Mouth Disease Vaccine Production Facility*

Products:
– Viral veterinary Vaccines
– Foot and Mouth Disease Trivalent Vaccine
– Rabies Vaccine
– Sheep Pox Vaccine
– Bacterial Veterinary Vaccines
– Rinderpest Vaccine
– Tetanus Vaccine

[25] Press statement to As-Sabah by the Ministry of Labour and Social Affairs who is lending the money: ID 9,651,684,000.

4.3.2.1.7 *State Company for Drug Industries – Nineveh (Mosul)*[26]

The Nineveh State Company for Drug Industries was formerly a part of the state controlled conglomerate for the production of pharmaceuticals and medicaments. It was incorporated as a separate entity in 2002. Accounts and basic information about the company are given in Appendix B.

The company comprises a main facility for the production of the pharmaceuticals and a dedicated IV saline plant. It also states that the productions units are new and modern.

Since incorporation it states that it has completed the building of a cancer product manufacturing unit and an antibiotic production unit, though it is believed that these are not yet operating. The company states an intention to expand by completing a unit for the production of inhalers.

Production

Table 4.3.2.1.7 gives the production capacity and production figures for the presentations manufactured by the factories. Production is described as: tablets; capsules; ointment and cream; syrup and drugs for the treatment of cancer.

Table 4.3.2.1.7 Nineveh Pharmaceutical factory production

PRODUCTS	UNIT MEASUREMENT	DESIGN CAPACITY	AVAILABLE CAPACITY	2002 PRODUCTION
Tablets	Millions	1,080	810	540
Syrup	1,000 Bottles	17,550	6,000	6,000
Oral Drops	1,000 Bottles	9,200	1,500	1,500
IV Fluid	1,000 Bags	2,835	3,600	3,600
Eye Drops	1,000 Bottles	6,750	2,400	2,400
Ointments	1,000 Tubes	7,200	6,000	6,000
Capsules	Millions	405	180	180
Suppositories	1,000	10,620	800	800

Therapeutic areas include:
– Antibiotics
– Anti-cancer

Raw materials

Raw materials to USP 23 and BP98 standards are imported, and these are mainly sourced from Italy, India China and Germany. See raw materials under Samarra.

Financial Information

A full financial schedule for the years 2002-2004 inclusive is given in Appendix B. It is noted that these figures differ from the ones presented in the company's web site and the equivalent Ministry of Industry and Minerals publication on the SOEs for 2002.

[26] The information is extracted from the web site of the Ministry of Industry and Minerals and a CD/brochure prepared by the Ministry on the State Owned Enterprises in 2005.

A summary of these accounts for 2004 are:

Total assets of ID 13,831,079,000; total income of 7,191,596,000, with a net profit of 704,061,000, or 9.8% (USD[27] Assets: 9,408,897, revenue 4,892,242 net profit 479,518).

The company's figures for 2002 are earnings of ID 5,115,000,000 or USD 1,739,100[28]. The company also reports for the same period fixed assets at 1,811,000,000 ID, or USD 615,740 and a Certified Capital of 2,084,000,000 or USD 708,560.

Employees

Employees are stated at 973, comprising 602 in production and 371 in administration.

4.3.2.1.8 *State Companies for Drug Industries – Samarra*

The state company was claimed as one of the largest pharmaceutical manufacturing facilities in the Middle East, founded in 1957 as the principal domestic manufacturer of medicines. It consisted of the five listed facilities and manufactures a large range of products in a variety of formulations. In addition it manufactures some animal medications. It boasts a knowledgeable and skilled workforce, new equipment (at the time of reporting for 2002) including blister pack machines.

It comprises:
- Samarra Drug Factory
- Baghdad Factory for Medical Gases
- Babylon Factory for Disposable Syringes and Medical Gases

See the relevant sections above for details.

The company has a development strategy that includes erection of a new facility (Ibn Sina) for the production of syrups, drops and antibiotics, and the rehabilitation of the quality control building and the development of an eye drops project.

Equity Holdings

In 2003 it was reported (CPA[29]) that the company also has equity holdings in the Akai company in Iraq, and in companies in Jordan and the UAE.

Production

The company reports manufacturing over 300 medical formulations, these are listed in table 4.3.2.1.8 below.

[27] 2004 Exchange rate, USD1 = ID 1,470
[28] At an average exchange rate for 2002 of 1 USD =ID 2,941.176
[29] State Owned Enterprises – Company Overviews – OCPA – Ministry of Industry and Minerals; Coalition Provisional Authority 2003.

Table 4.3.2.1.8 (a) production – tablets

Algesic	Libisex	Samavit B-Co
Allermine	Libraxam	Samavit B6
Asmasam	Metheprim	Samavit C
Asprin, adult	Multisamavit M	Sameron
Asprin, infant	Paracetol	Sedilar
Coldin	Prisolone	Tetravit
Flu	Rheuma	Travemine
Gastrigel	Samafurantin	Valiapam
Largapromactil	Samalgin	

Table 4.3.2.1.8 (b) production – capsules/ampoules

Allermine	Erythromycin	Samaphenicol
Ampicillin	Hemavit	Samavit B12
Atropine Sulfate	Prenavital	Tetravit
B Plex	Samacycline	

Table 4.3.2.1.8 (c) production – ointments

Algesin	Dermocure HC	Samacycline Ophthalmic
Betnosam	Hydrocortone N	Samaphenicol Eye
Betnosam N	Nystacort	Smicks
Burn cream	Rheumalgin	Zinc Castor Oil
Dermocal Cream		

Table 4.3.2.1.8 (d) production – syrups/drops

Allermine syrup	Ferrosam syrup	Samavit B-Co syrup
Ampicillin drops	Hypnoral syrup	Samavit C drops
Antipyrol drops	Multisamaplex syrup	Samilin syrup
Antipyrol syrup	Nasophrine nasal drops	Sedilar drops
Antispasmine drops	Neo-dexon eye/ear drops	Spastal pediatric drops
Bronchodil infant syrup	Otocaine ear drops	Toniphos syrup
Calcium/Vit B12 syrup	Piperazine citrate elixir	Tussilet syrup
Coldin syrup	Pulmocodin syrup	Tussiram syrup
Ferro B elixir	Samacetamid eye drops	Zincosulf eye drops

It is reported that a phial line is in place in the factory, however it is not currently operating.

Raw materials

Raw materials to USP 23 and BP98 standards are imported; active ingredients are all imported, generally from wholesalers in Jordan/Syria as the quantities purchased tend to be small. Excipients (colorants/flavours, sugar etc) tend all to be purchased from Shorja – the largest wholesaler.

Financial Information

The company reported earnings in 2002 of ID18,055,000,000 or USD 6,138,701[30]. It is assumed that these are net earnings.

[30] At an average exchange rate for 2002 of 1 USD = ID 2,941.176

The company also reports for the same period fixed assets at 4,282,000,000 ID, or USD 1,455,880 and a Certified Capital of ID 1,772,000,000 or USD 602,480.

Current gross earnings are understood to be 3 billion ID per month with a reported nominal margin of 50%[31].

Employees

Employees are stated at 3,220, comprising 2,836 in production and 384 in administration.

Pricing and Margin

In 2003 the pricing regimen was described as cost plus 30%, with the company running on a low margin, with no proper depreciation or re-investment programme. It was also reported that prices were some 30-40% cheaper than imported products.

Production Costs

It was reported that the majority of costs are associated with the import of raw materials, and packaging materials.

4.3.2.2 Private Sector

The manufacturing companies in the private sector tend to be small and to produce topical medicines, with no specialist products.

There are 15+ private manufacturers, principally focusing on tablets and syrups. This group itself comprises two sections, a legally monitored and established private sector industry, and more recently illegal and unregistered manufacturers. This section will examine the former. The private sector went through a development process dictated by the competence of the respective plants to manufacture, therefore production units focused on, in turn; syrups come first as they are the easiest to manufacture (but do not overall have a high margin), then tablets, because of the huge demand – particularly for simple analgesics – paracetamol – for example. Iraqi current demand is for some 13 billion tablets p.a., of which approximately 4 billion are domestically manufactured. The balance are imported.

Subsequently ointments, creams are manufactured, with domestic manufacture supplying some 20% of total demand; then comes parenteral solutions, i.v. fluids and injection lines. This is followed by the manufacture of suppositories, rectal and vaginal.

There is no private manufacturing facility for phials – though cost of production is relatively low for a high margin product, the manufacturing facility has a high capital cost requirement to achieve, and maintain the standards required of GMP (good manufacturing practice).

All these companies are small, with relatively low gross revenues.

[31] Personal communication

The top companies are:

1. Thafor: Manufacturer of tablets and suppositories. It was noted that in 2000 the manufacturing line cost less than USD 750,000.

2. Al Mansour: A traded joint stock company with a significant ownership by the 'Pharmacists Syndicate'. In 2004 the company demonstrated a sales revenue of ID 390 million on which it showed a small loss of ID 3 million. Iraq stock exchange information is appended at Appendix C.

3. Asharq Alawasit (Middle East Company): Described as the most competent.

4. Akai: The biggest in the private sector. Established by an Indian company the company is now owned by the Arab League. The company produces antibiotics, in a filling, labelling and packing operation.

5. Al Forat: Produces cough medicines and paracetamol.

6. El Shahid: This company pioneered the manufacture of cough syrups in Iraq.

Since the 2003 war there has been an increase in the number of unlicensed manufacturers, possibly up to 18, with little, or none, supervision by the regulatory authorities resulting in a consequential lack of GMP[32], and obvious effects on healthcare.

In the animal medicine/veterinary side, one company is listed, and traded on the stock exchange:

1. Al-Kindi for the Production of Veterinary Vaccines and Drugs. This company was established in 1990, and on sales of ID 420 million showed a profit of ID 77 million (approximately USD 55,000) in 2004. The Company's annual return is in Appendix C.

4.3.3 Imports

4.3.3.1 Sources of Origin

The author was not able to access import statistics for Iraq, therefore the sources of origin were compiled from two principal sets of sources; the export statistics of individual countries or blocks of countries where available; and Comtrade – the trade database of the UN. A full compilation of this data is given in Appendix D, for the period 1980 to 2005.

The principal sources are the EU 25, notably France, Belgium and Germany, Switzerland, India, Jordan, with smaller quantities from Iran and Dubai, then with very low volumes emanating from a broad spectrum of countries[33].

Table 4.3.3.1 gives a summary of the values of reported exports to Iraq in the pharmaceutical, drugs and consumables listed as in HS chapter 30 (including 3006).

[32] Personal communication

[33] These additional countries include Bulgaria, Canada, Chile, Colombia, Hungary, Korea, Mexico, Morocco, Norway, South Africa, Sweden and Macedonia

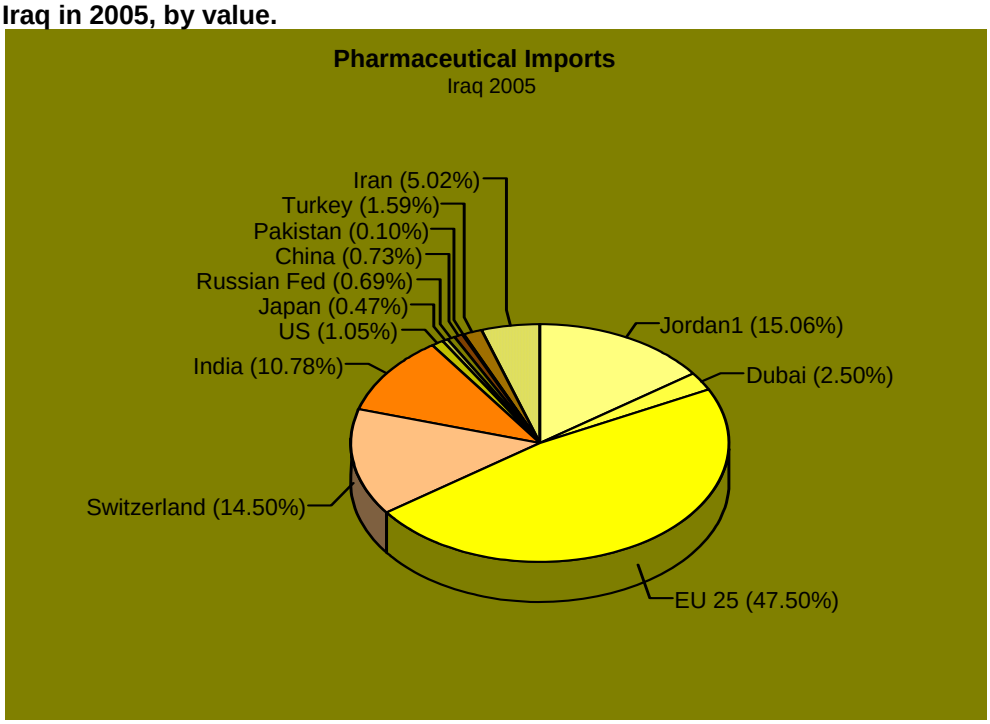
These are given in totals, to quantify the potential size of the market; the numbers are then broken down into categories further in the chapter.

Table 4.3.3.1 Summary table of pharmaceutical reported exports to Iraq[34]

Source	1999	2000	2001	2002	2003	2004	2005
Jordan				48,182,236	39,233,885	30,551,578	25,679,119
Dubai							4,269,453
EU 25	25,098,430	41,823,289	54,835,458	67,199,639	67,440,699	72,001,677	80,975,996
Switzerland				15,218,898	5,892,771	51,080,327	24,723,158
India			5,040,000	7,270,000	7,820,000	30,080,000	18,370,000
US		0	0	0	178,000	2,137,000	1,793,000
Japan				2,226,874	794,360	257,519	795,130
Russian Fed				5,399		524,679	1,170,374
China				4,785,260	2,550,605	471,214	1,246,905
Pakistan					12,509	69,832	174,056
Turkey					1,921,404	2,115,399	2,715,324
Iran					3,301,806	5,862,200	8,550,850
TOTAL	25,098,430	41,823,289	59,875,458	144,888,306	129,146,039	195,151,425	170,463,365

Notes:
These figures are by reported values, where domestic sources discuss volumes, the comparative should be noted. The US figures given in the table are from the TradeStats Express – National Express Database, which is categorized as per the HS chapters and sections. Other categorizations used by the US authorities include the five figure end use code for pharmaceutical preparations of 40100 which then offers the following figures for exports to Iraq in value: 2003, USD 7,267,000; 2004, USD 2,151,000; and 2005, USD 2,787,000. In addition the three figure SITC code is used – 542, Medicaments (including veterinary medicaments) - which offers an FAS value of exports to Iraq of USD 130,000, and 541 medicinal and pharmaceutical products, other than medicaments (of group 542), which offers a figure of USD 1,731,000 for the same year.

Graph 4.3.3.1 Pie chart representing sources of pharmaceutical reported exports to Iraq in 2005, by value.



[34] Sources: Jordan; Comtrade, Dubai; Dubai Customs Authority/Dubai World, EU 25, Eurostat, Switzerland, Comtrade, India Department of Commerce; Export Import Data Bank, USA; US Census Bureau, Japan, Russian Fed, China, Pakistan, Comtrade.

Within the Iraqi domestic market are also reported significant quantities of products of Egyptian and Syrian origin, though these are reported as part of the longitudinal study in the next section the recorded volumes are low. Both countries have an active pharmaceutical manufacturing sector, not dissimilar to that of Jordan, producing generics, reformulations largely exported to the MEA region.

4.3.3.2 Longitudinal study

Table 4.3.3.2 shows the total pharmaceutical spend in USD (nominal, unadjusted) for the period 1980 to 2005[35] with the nominal amount per capita spend. Graph 4.3.3.2 demonstrates this.

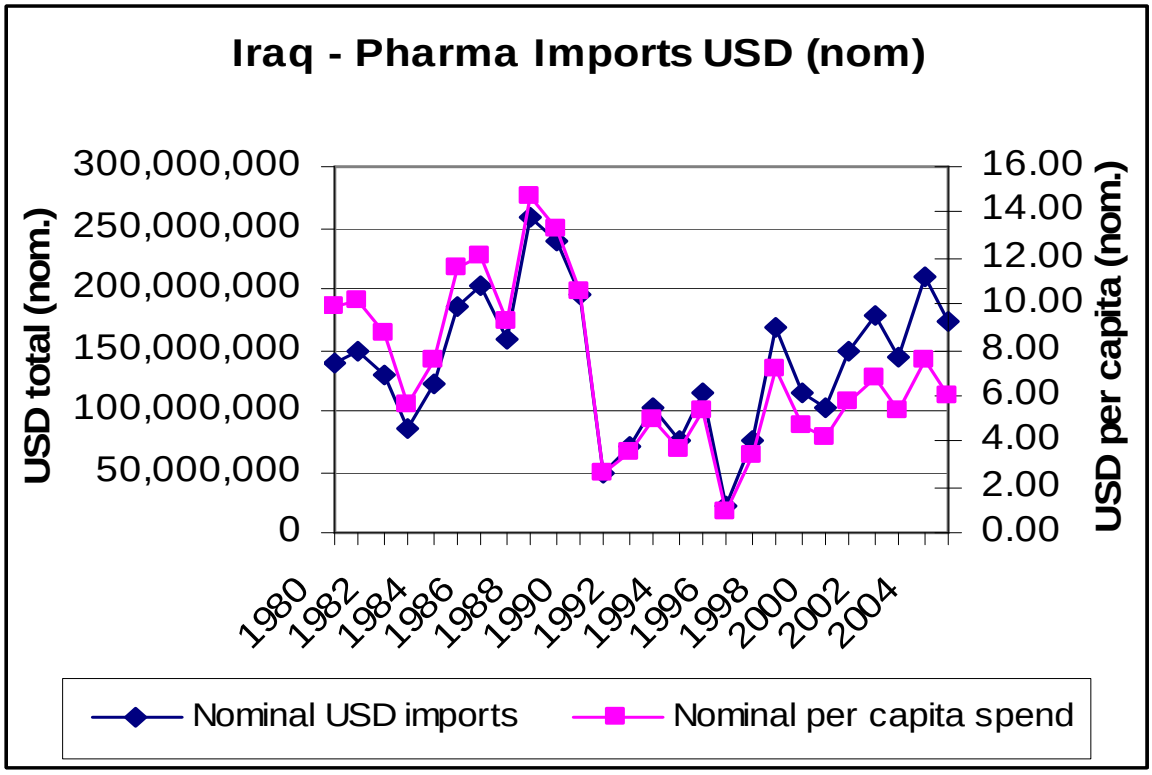
Table 4.3.3.2 Gross USD spent on pharmaceutical imports 1980 – 2005 with per capita[36] nominal expenditure

Year	**1980**	**1981**	**1982**	**1983**	**1984**
USD	139,303,675	147,860,611	130,108,337	85,904,365	120,813,379
Pop (mill)	14	14.531	14.974	15.417	16
USD per capita	9.95	10.18	8.69	5.57	7.55
Year	**1985**	**1986**	**1987**	**1988**	**1989**
USD	185,095,081	201,533,669	158,669,875	258,638,372	238,796,578
Pop (mill)	16	16.71	17.127	17.554	18.012
USD per capita	11.57	12.06	9.26	14.73	13.26
Year	**1990**	**1991**	**1992**	**1993**	**1994**
USD	195,651,506	49,740,973	70,305,192	101,391,816	76,320,755
Pop (mill)	18.515	19.07	19.672	20.309	20.967
USD per capita	10.57	2.61	3.57	4.99	3.64
Year	**1995**	**1996**	**1997**	**1998**	**1999**
USD	115,620,749	21,065,038	76,785,334	169,347,221	114,080,279
Pop (mill)	21.632	22.301	22.977	23.662	24.36
USD per capita	5.34	0.94	3.34	7.16	4.68
Year	**2000**	**2001**	**2002**	**2003**	**2004**
USD	103,025,769	148,089,234	178,194,896	143,134,293	210,225,234
Pop (mill)	25.075	25.806	26.55	27.03	28.057
USD per capita	4.11	5.74	6.71	5.30	7.49
Year	**2005**				
USD	174,179,699				
Pop (mill)	28.807				
USD per capita	6.05				

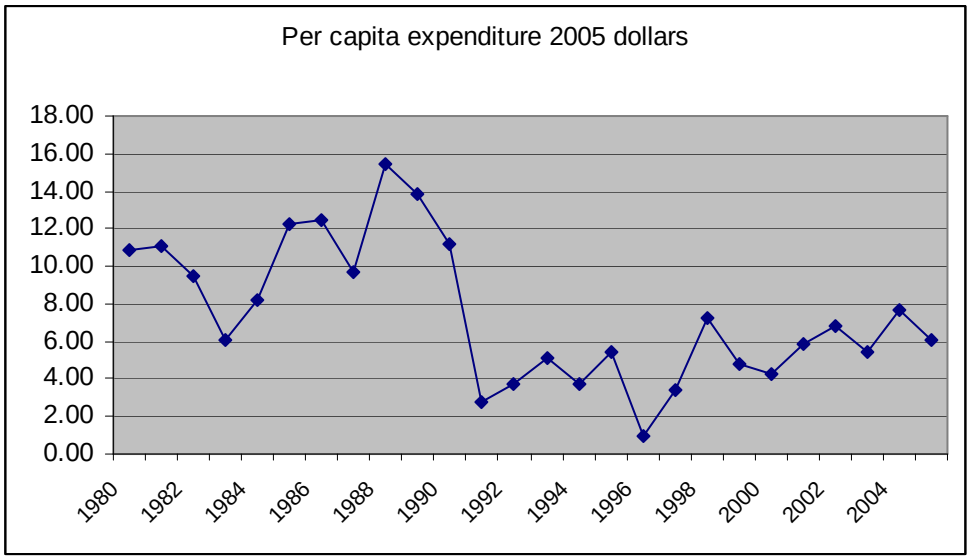
[35] SITC Section 54 Medicinal and pharmaceutical products: Comtrade

[36] Population statistics: Informal communication; the figures represented here are possibly true for a theoretical entire population with no discount for the current mortality rate and the rapidly increasing migration. For the latter, figures may be estimated in Jordan from the family registration cards issued: At the end the of 2005 such a card had the serial number in the 649,000's, thus suggesting given a family size of four, a Jordanian Iraqi population of not less than 2.6 million, however Jordanian authorities estimated ½ million, and current figures assume 1 million each in Jordan and Syria through the formal and informal migration to Syria, estimated (BBC) at 750,000, in addition there are 150,000 in Egypt (UNHCR). There are communities further afield, and if these are taken into account, then should be added total populations (electoral commission list) Australia, Canada, Denmark, France, Germany, Iran, Jordan, The Netherlands, Sweden, Syria, Turkey, the UAE and the USA. IECI estimated 4 million voters at end Dec 2005. With an informal estimate of up to 655,000 dead (Lancet, though there is much discussion about the size, the number of violent deaths is significant.) a conservative estimate of loss of domestic population is approximately 5 million. This equates to approximately 17% of the population. It is also worthy of note that a disproportionate number of the middle/professional classes have left, denuding the state of essential skill sets.

Graph 4.3.3.2 (a) Iraq pharmaceutical imports 1980-2005 USD nominal



Graph 4.3.3.2 (b) Adjusted pharmaceutical spend USD/capita 1980-2005



4.3.4 Estimates of Current Market Size

A nominal valuation of the sales revenue from the public sector is a revenue of some USD 20 million based on the 2002 figures, and personal communication. The figure for the private sector is an estimate, based on the figures for Al Mansour with a revenue of

approximately USD 270,000 in 2004. If all fifteen registered companies have the same order of revenue, that means a realistic maximum revenue of about USD 4 million.

The two figures respectively of domestic manufacture, by value, (24 million) and imports (174 million) thus suggest a potential total domestic pharmaceutical market, by value, of USD 198 million.

This offers a domestic pharmaceutical expenditure of approximately USD 7.3 per capita, which is significantly below that of OECD countries.

There are considerations as noted that these figures do not accurately reflect actual expenditure, for example, it is reported that annual average expenditure on general antibiotics is USD 50 million annually and for Mobic (meloxicam) is USD 4.5 million.

In 1989 the MoH reported spending[37] USD 360 million for imported pharmaceuticals, vaccines, medical appliances and disposable supplies; USD 100 million for raw materials for the state manufacturing operations, and a further USD 30 million for spare parts and the maintenance of health service equipment[38].

In response to the sanctions drug supply was rationed, and that between 1990-97 the WHO estimated that the government contributed USD40-50 million p.a. approximately 10-15% of needs.

4.4 Estimate of Potential Market Size

4.4.1 Introduction

To estimate the potential size of the market in stable Iraq key indicators of total population and per capita spending in markets of a similar demographic profile may be made, and these in turn compared with markets with, for example larger GDP per head. In addition, to understand some of the shape of the market the morbidity and mortality statistics can indicate where market opportunity and development might lie.

Taken together these figures can then give an indication of the range of total potential market size and the sector profile.

4.4.2 Drug Spending Per Capita

Spending on pharmaceuticals is given for 1996 in table 4.4.2, extracted from a study[39], and then in graph 4.4.2 this expenditure is compared with the GDP per capita for those countries where both data sets were available (note the data set for GDP is 1997, one year later, however the comparison would appear valid).

The findings of the study showed that there was a general uniformity across the OECD nations on the level of per capita spending on pharmaceuticals (median expenditure of USD 234, mean 240, standard deviation of 58, maximum of 349 and minimum of 126 USD). The relationship between GDP per capita (adjusted for PPP) and the spend is practically flat, indicating that amongst the OECD there is no real trend between increased GDP and overall spend on pharmaceuticals. However, it could be assumed that these

[37] Cited in Medicines and Medical Supplies. United Nations Development Group. http://iraq.undg.org
[38] And USD 10 million for ambulances and logistical vehicles

countries have reached the optimum level of expenditure. Where a country has a low per capita GDP and low overall healthcare expenditure, it may be assumed that a relationship may well exist between an increase in GDP and an increase in healthcare expenditure.

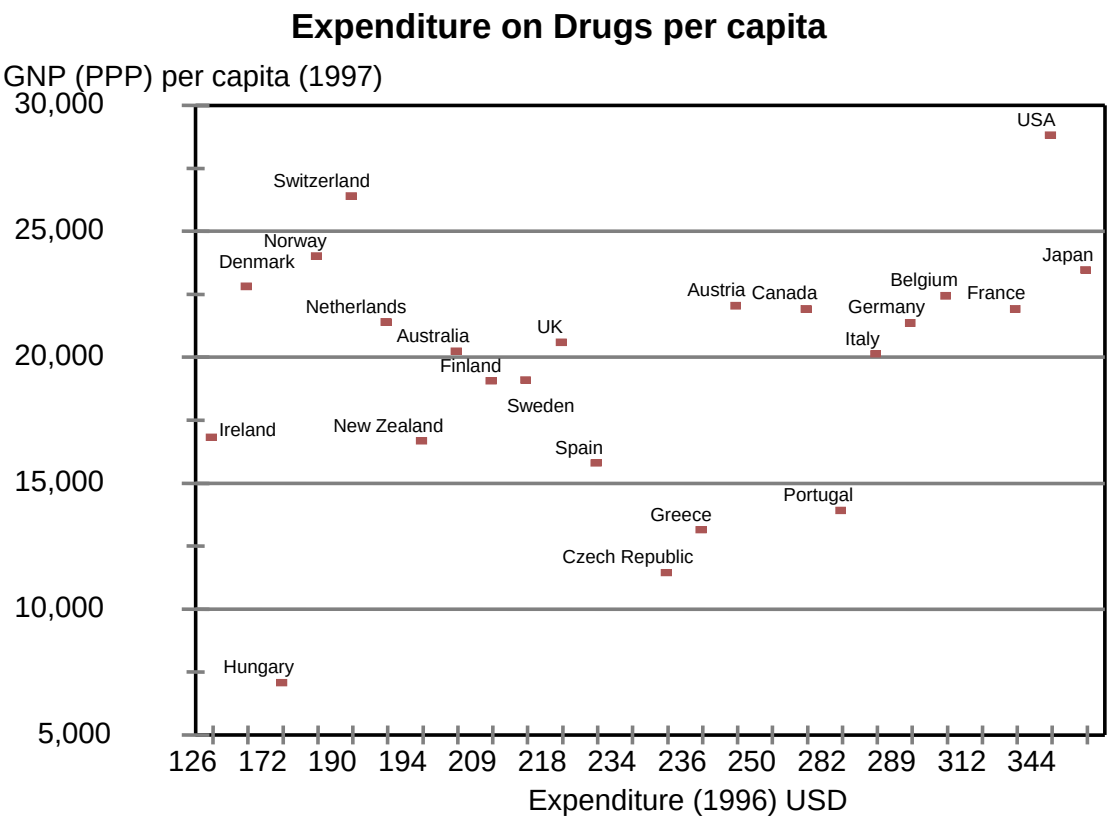
Amongst the OECD there is much greater variation in the proportion of healthcare expenditure which is spent on pharmaceuticals. This is shown in Graph 4.2.2 (b), showing that as GDP/capita increases the proportion of healthcare expenditure dedicated to pharmaceuticals decreases. The authors hypothesise that this is related to the purchase of pharmaceuticals on the international market, whereas the balance of healthcare is purchased domestically (usually).

Table 4.4.2 Drug spending per capita shows the spending per capita for OECD countries[39] 1996

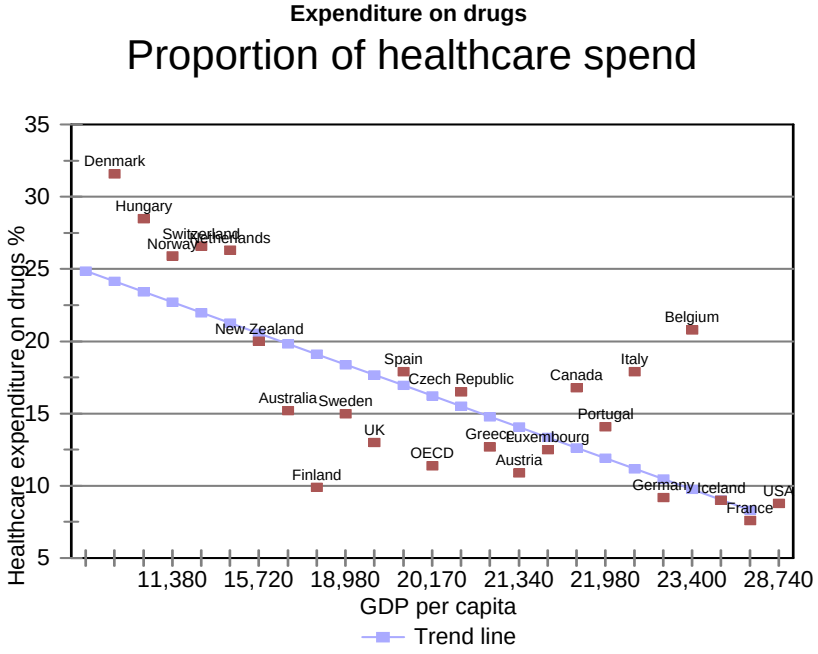
Country	Drug spending per capita USD	Physician visits per capita	Percent of total health spending on drugs %	GDP per capita (1997)
Australia	202	6.6	11.4	20,170
Austria	247	6.3	14.1	21,980
Belgium	306	8.0	17.9	22,370
Canada	258	6.5	12.5	21,860
Czech Republic	234	Na	25.9	11,380
Denmark	165	5.4	9.2	22,740
Finland	209	4.1	15.	18,980
France	337	6.5	16.8	21,860
Germany	289	6.4	12.7	21,300
Greece	236	Na	26.6	13,080
Hungary	172	14.8	28.5	7,000
Iceland	312	4.8	16.5	n.a.
Ireland	126	Na	9.9	16,740
Italy	284	Na	17.9	20,060
Japan	349	15.8	20.8	23,400
Korea	Na	9.5	Na	13,500
Luxembourg	250	Na	11.7	
Mexico	Na	2.1	N	8,120
Netherlands	193	5.7	10.9	21,340
New Zealand	194	Na	15.2	16,600
Norway	174	Na	9.0	23,940
Poland	Na	5.4	Na	6,380
Portugal	282	3.2	26.3	13,840
Spain	223	N	20.0	15,720
Sweden	218	3.0	13.0	19,030
Switzerland	190	Na	7.6	26,320
Turkey	Na	Na	31.6	6,430
UK	218	5.9	16.5	20,520
USA	344	6.0	8.8	28,740
OECD	234	5.9	15.9	

[39] Extracted from Exhibit 5, Anderson, Gerard F and Poullier, Jean-Pierre. Health Spending, Access and Outcomes: Trends in Industrialized Countries. Health Affairs 18 (3) 178-192. 1999. Sourced OECD Health Data 98: A comparative analysis of twenty-nine countries. OECD 1998.

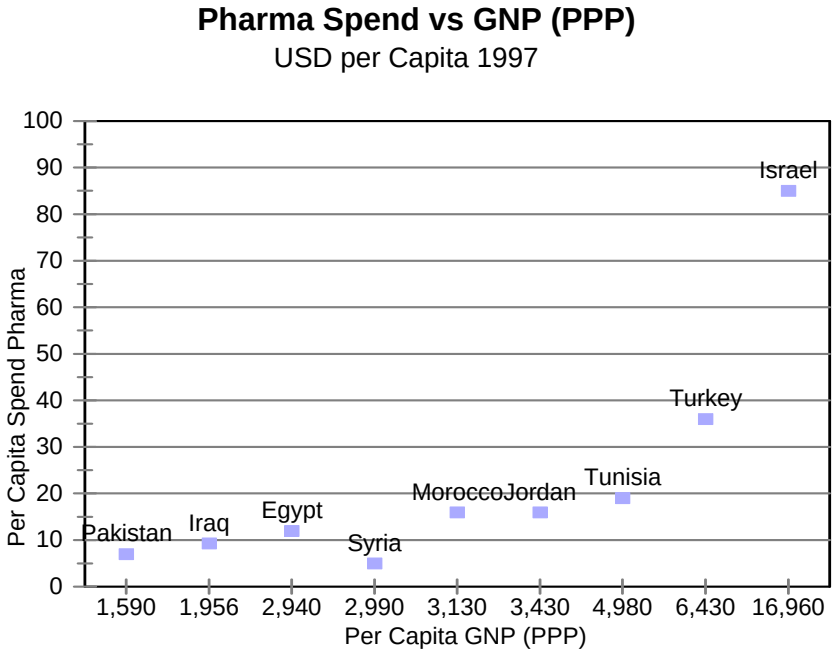
Graph 4.4.2 (a) OECD Expenditure on pharmaceutical products (drugs) per capita[39]



Graph 4.4.2 (b) Proportion of GDP spent on healthcare against GDP per capita

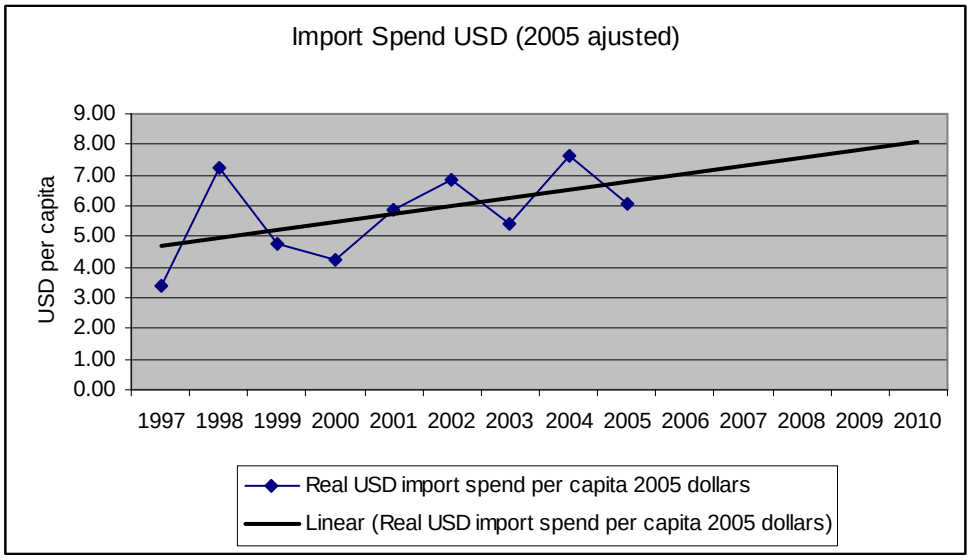


Graph 4.4.2 (c) Pharmaceutical spend versus GNP for Iraq and regional neighbours 1997[40]



Graph 4.4.2 (c) shows the pharmaceutical spending against per capita GNP for regional countries. This graph is meant to demonstrate that the pharmaceutical spending per capita of Iraq is in line with regional norms (GNP was estimated, see footnote). Graph 4.4.2 (d) demonstrates the Iraqi spend per capita with the associated linear trend line.

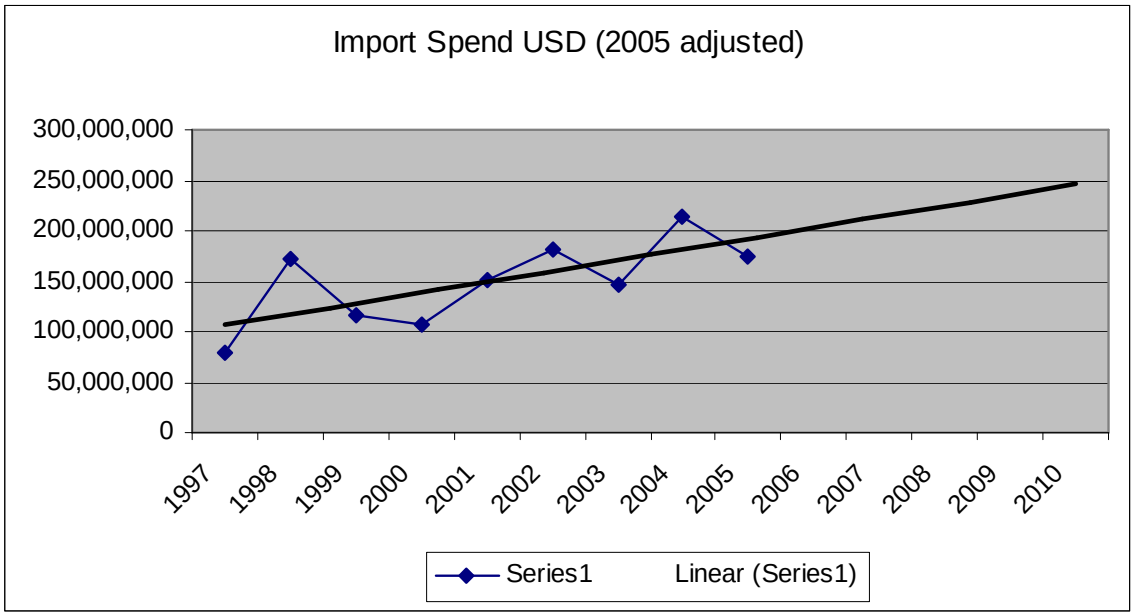
Graph 4.4.2 (d) Import spend (adjusted to 2005 dollars), with the linear trend line to demonstrate potential pharmaceutical spending



The graph thus indicates that five years out from 2005 (2010) the current trend indicates a spend of USD 8.00 per capita, the range is approximately +/- USD 1.2, therefore an approximate spend might reach USD 9.20 per capita, if current conditions prevail.

[40] Source for GNP: World Development Report 1998/99 Key Economic Indictors: that for Iraq was taken as the mean of the range for the lower middle income group as per footnote (g) of Table 1(a) op cit.

Graph 4.4.2 (e) Total USD import spend adjusted 2005 dollars with trend



On the basis of the foregoing the total potential market as given in graph 4.4.2 (e) is some USD 250 million, plus (or minus) the annual variance, the local public sector and private sector components.

4.4.3 Additional Sources of Supply

The formal means of supply are the private and public sector, in addition there is the black market, where participants recognise its illegality but are relatively informed, and the grey market, which is illegal, and many participants are uninformed; and additionally, the NGO imports. In particular the latter can be quite significant in certain areas, e.g. in child care (UNICEF) emergency relief (UNHCR). In terms of statistical reporting, many of the NGO products will be reported in customs declarations, however where they are not, the total consumption cannot be reported accurately. However, in terms of total potential market, on a commercial basis the figures as reported appear to be the most appropriate and best available.

4.5 Regional Market Comparisons

The paragraphs below look at the markets in a number of Near/Middle East countries.

4.5.1 Egypt

Multi-nationals account for probably some 65% of the USD 1.6 billion Egyptian market, direct local manufacture (30%) and 35% licensing agreement with Egyptian companies. The AstraZeneca company doubled employment to 350 people, USD32 million investment, capacity 250 mill tabs per year able to expand to 400 million per year.

The market estimate offers a per capita consumption of this, the largest market in the Middle East/North Africa, of some USD 22 in 2006[41], with a market growth of 4%. It is acknowledged that this study is not a full formal meta-analysis of the regional markets, and that there are discrepancies amongst reported figures, however, these are considered indicative of market status. Also notable is the significant difference between these and OWCD reported expenditures. Within this lies another aspect, of taxes, controlled prices and pricing regimes, margins dissimilar markets.

There are approximately 30 pharmaceutical manufacturing companies in Egypt, most in the private sector, nine[42] of which are in the top 100 Egyptian companies by revenue, led by Egyptian International Pharmaceutical Industries Company (EIPICo) with a 2003 revenue of LE 535.3 million (USD 91.5 million). In addition most multi-nationals are present in the country, and developments have included the 1998 purchase of a 90% stake in Amoun Pharmaceuticals by GlaxoSmithKline and the development this year of a new manufacturing site by AstraZeneca with an investment of USD 32 million. Notably in the last instance reference was made to the compliance of Egypt with the TRIPS elements related to the WTO accession completed in 2005.

4.5.2 Syria

In 1998 it was reported[39] that there were two state owned manufacturing companies in Syria: Thameco, owned by the Ministry of Industry and Dimas, by the Ministry of Defence, though the private sector was developing. At the time of writing 56 private companies were manufacturing, supplying 89% of the country's needs, 70% under special licence. A number of the most significant are listed in the footnote[43].

Syria has applied for WTO membership however the application has not yet been accepted. In terms of TRIPS, in 2000 the government passed a copyright that extended patent protection to pharmaceutical NCEs[44] and increased patent protection to twenty years, thus bringing it into line with TRIPS requirements for WTO accession.

4.5.3 Iran

In 1997 the total pharmaceutical sales were estimated at 1,045 million USD[45], though another source[46] estimated at 1999 sales of only USD 600 million, representing pharmaceutical spending of USD 9 per capita. It was reported that in 1991 there were some 39 operating production units, and by 1995 these were supplying 93% of domestic pharmaceutical requirements, though this is believed now to have reduced to around 80-85% with the balance imported. The majority are state owned companies, with a small

[41] Pharma Outlook Quarter 1, 2006: Espicom Business Intelligence.
[42] [Company, (2003 revenue) EIPICo (536); Medical Union Pharmaceuticals (331); Pfizer Egypt (278); Amoun Pharmaceutical an Chemical Industries (259); Nile Pharmaceuticals and Chemical industries .Company (259); Cairo Pharmaceuticals and Chemical Industries Co (197); Alexandria Pharmaceuticals and Chemical industries (191); Memphis Pharmaceuticals (142) Arab Drugs and Chemical Industries (134). Net profit margins range for these from 13% (Arab Pharma. 2006) to 24% (EIPICo 2005) and for listed Pharco 48%.
[43] Adamco Pharmaceutical Industries; Aleppo Pharmaceutical Industries; Al Fares Pharmaceuticals; El Saad Pharmaceuticals; MBC Pharmaceutical Industries; Medipharm; Oubari Pharmaceutical Products; KC Pharma; Unipharma; Barakat Pharmaceutical Industries.
[44] SABA Bulletin November 2000.
[45] Source: World Drug market Manual 1998: Asia, Africa & Australasia. IMS World Publication 1998.
[46] Healthcare Markets Fact Book 2003. Espicom Business Intelligence May 2002.

minority operating in the nascent private sector. The twenty largest belong to the Pharmaceutical Industry Group within the National Iranian Industries Organisation.

It is noted that 85% of pharmaceutical raw materials were imported, and of finished product there was a small amount of exports. Further details may be explored through reference (45).

4.5.4 Jordan

Prior to 2000 the country was typical of the region, importing raw materials and formulating/reformulating patented products as well as, frequently with Indian assistance, reverse-engineering patented products. There are 15 manufacturers of pharmaceuticals in Jordan (as of December 2005[47]), but four of them[48] have some 90% of the market. Most of the newcomers that entered the market after 1990 were encouraged by the potential opportunities of breaking patents and the lucrative export market the Arabic non-signatories to the WTO, at that time of Iraq, Saudi Arabia and Algeria, for example.. In 2001 the country signed a free trade agreement with the USA that required it alter its patent/copyright law to reflect international agreements on intellectual property, and the Drug Producers Federation said that the agreement confirmed their commitment to that.

In addition as Jordan applied to the WTO at that same time the new laws have to comply with the TRIPS requirements of accession.

4.5.5 Saudi Arabia

Saudi Arabia does not manufacture significant quantities of pharmaceutical products, though it imports semi-finished product which is then repackaged, labelled and exported. The market is significant, with imports of some USD 1.5 billion. The country has applied for WTO accession, and as a part of the process has to resolve its complicated sets of laws regarding patents.

4.6 Market Segmentation by Therapeutic Area

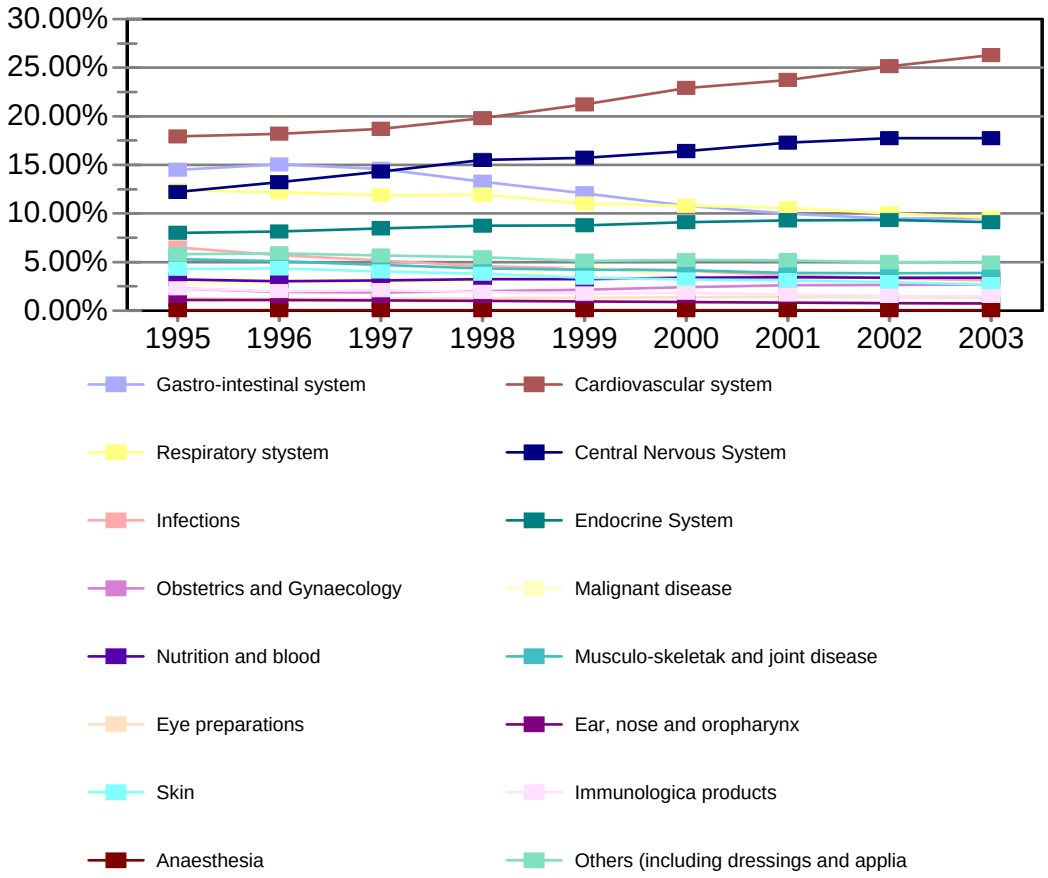
Table 4.6 and graph 4.6 show the split in pharmaceutical spend in a typical OECD country (United Kingdom) this is purely shown for exemplary purposes only, but does demonstrate the high and increasing spend on cardiovascular products, CNS products and the significant decrease in GI products.

[47] World Pharmaceutical Market: Espicom Business Intelligence. December 2005
[48] Arab Pharmaceutical Manufacturing Company, Dar al Dawa, Hikma Pharmaceuticals, JPM

Table 4.6 Cost of prescriptions dispensed in various disease areas UK 1995-2003 USD millions[49]

	1995		1996		1997		1998		1999		2000		2001		2002		2003	
Gastro-intestinal system	956	14.51%	1,158	15.06%	1,283	14.61%	1,287	13.27%	1,281	12.08%	1,130	10.80%	1,087	9.97%	1,202	9.48%	1,334	9.53%
Cardiovascular system	1,180	17.91%	1,401	18.22%	1,644	18.70%	1,921	19.82%	2,251	21.22%	2,398	22.92%	2,587	23.74%	3,192	25.17%	3,684	26.31%
Respiratory system	817	12.40%	935	12.16%	1,046	11.90%	1,156	11.92%	1,170	11.03%	1,129	10.79%	1,149	10.54%	1,269	10.01%	1,337	9.55%
Central Nervous System	805	12.21%	1,016	13.21%	1,259	14.33%	1,504	15.51%	1,668	15.73%	1,717	16.41%	1,884	17.29%	2,253	17.76%	2,485	17.75%
Infections	429	6.51%	438	5.70%	455	5.18%	445	4.60%	461	4.35%	430	4.11%	394	3.62%	423	3.33%	436	3.12%
Endocrine System	527	8.00%	627	8.16%	745	8.48%	845	8.71%	930	8.77%	950	9.08%	1,011	9.27%	1,184	9.33%	1,275	9.11%
Obstetrics and Gynecology	151	2.30%	148	1.93%	165	1.88%	195	2.02%	228	2.15%	256	2.44%	284	2.60%	339	2.67%	379	2.71%
Malignant disease	185	2.80%	222	2.88%	257	2.92%	293	3.02%	493	4.65%	351	3.35%	373	3.42%	435	3.43%	483	3.45%
Nutrition and blood	211	3.21%	231	3.00%	273	3.11%	316	3.26%	343	3.23%	354	3.38%	376	3.45%	430	3.39%	477	3.40%
Musculo-skeletal and joint disease	349	5.29%	390	5.07%	416	4.73%	421	4.34%	447	4.21%	437	4.18%	423	3.88%	490	3.86%	544	3.89%
Eye preparations	85	1.29%	92	1.20%	110	1.25%	124	1.28%	139	1.31%	144	1.37%	154	1.41%	174	1.37%	183	1.31%
Ear, nose and oropharynx	73	1.10%	84	1.10%	92	1.04%	99	1.02%	100	0.95%	92	0.88%	91	0.83%	99	0.78%	105	0.75%
Skin	284	4.31%	334	4.34%	355	4.04%	368	3.79%	361	3.40%	333	3.18%	338	3.10%	370	2.92%	379	2.71%
Immunological products	151	2.30%	156	2.03%	183	2.09%	185	1.91%	184	1.74%	192	1.84%	181	1.66%	189	1.49%	204	1.46%
Anaesthesia	3	0.05%	3	0.04%	5	0.06%	5	0.05%	5	0.05%	5	0.04%	4	0.04%	6	0.05%	6	0.04%
Other (including dressings and appliances)	382	5.80%	454	5.91%	499	5.68%	530	5.47%	542	5.11%	546	5.22%	561	5.15%	629	4.96%	689	4.92%
TOTAL	6,590		7,688		8,788		9,695		10,604		10,464		10,897		12,684		14,000	

[49] Source: UK ABPI: figures converted to USD at prevailing exchange rate


30.00%
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1995
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Cardiovascular system
Respiratory stystem
Central Nervous System
Infections
Endocrine System
Obstetrics and Gynaecology
Malignant disease
Nutrition and blood
Musculo-skeletak and joint disease
Eye preparations
Ear, nose and oropharynx
Skin
Immunologica products
Anaesthesia
Others (including dressings and applia

5.0 MEDICAL PRODUCTS SECTOR

5.1 Introduction and Definition

Table 5.1 gives abbreviated selected headings from the Harmonisation Code for medical appliances and devices. This defines the area of study for this report. Section 5.2 gives the actual import figures for this area and looks at comparative data for the region.

Table 5.1 selected HS headings of Section 18 Chapter 90, Heading 9018 ff

	HS Code
ECG machines	90181130
Ultrasonic scanning apparatus	90181200
MRI scanners	90181300
Scintigraphic apparatus	90181400
Electro-diagnostic apparatus	90181900
UV/IR Equipment	90182000
Syringes	90183100
Tubular needles for sutures etc	90183200
Needles, catheters etc	90183900
Dental drill engines	90184100
Dental Instruments	90184900
Ophthalmic Instruments	90185000
Other medical instruments & appl.	90189000
Mechanical therapy appliances	90191000
Ozone/oxygen/aerosol therapy	90192000
Breathing appliances	90200000
Orthopaedic or fracture appliances	90210000
Artificial joints	90213100
Orthopaedic & fracture appliances	90211900
Artificial teeth	90212100
Dental fittings	90212900
Artificial parts of the body	90213000
Artificial joints for orthopaedic purps.	90213100
Artificial parts of the body	90213900
Hearing aids	90214000
(Heart) pacemakers	90215000
Articles or appliances, worn or carried	90219000
Computer tomography	90221200
X ray for dentistry	90221300
X-ray for medicine	90221400
X-ray – other	90221900
alpha, beta, gamma ray therapy	90222100
for other uses	90222900
X-ray tubes	90223000
X-ray generators, other	90229000

5.2 Medical Device Imports into Iraq

Iraq does not have a significant manufacturing industry in the defined areas, thus the total size of the market is effectively the import figures. In addition as most of these devices, appliances and consumables are being purchased through the MoH procurement system for supply to either the hospitals or specialist clinics, the gross official import figures should provide a good indication as to the size of the market.

This situation may change in the relative near future, however, with the announcement in February of 2007 of the construction of a factory for syringes (and the author assumes other medical equipment) funded by an Iranian initiative.

To look at the overall import trade of Iraq with the rest of the world, the five principal HS Headings have been taken as below (abbreviated):

Heading	Description
9018	Instruments and appliances used in medical, surgical, dental and veterinary …
9019	Mechano-therapy appliances, massage apparatus …
9020	Other breathing appliances and gas masks excluding protective masks …
9021	Orthopaedic appliance, including crutches, surgical belts and trusses
9022	Apparatus based on the use of X-rays or of alpha, beta or gamma radiation …

These are then tabulated in table 5.2, and the results, by source, graphically displayed in graph 5.2.

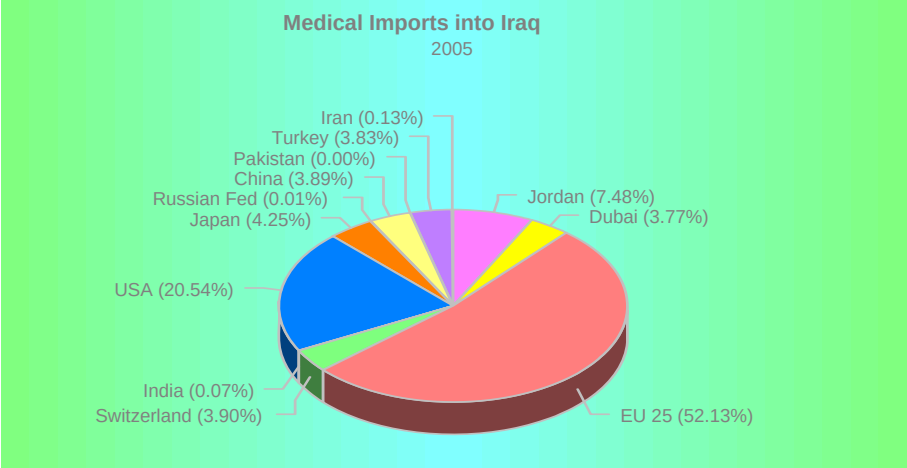
Table 5.2 Medical Products Exports to Iraq[50]

Source	H.S Heading	1999	2000	2001	2002	2003	2004	2005
Jordan	9018				8,731,059	31,340,976	7,440,510	5,880,806
	9019				18,299		93,311	49,585
	9020				1,410		6,266	21,691
	9021				1,379,618	184,537	1,687,902	440,183
	9022				158,351	197,184	410,800	293,403
Dubai	9018							3,152,739
	9019							44,217
	9020							410
	9021							156,015
	9022							15,248
EU 25	9018	30,870,620	32,429,721	96,659,992	95,517,521	48,849,828	26,744,418	40,415,355
	9019	801,338	1,105,497	4,622,138	13,610,132	3,970,524	2,586,108	1,091,784
	9020	0	285,569	0	102,756	25,889	1,002	76,775
	9021	2,044,125	2,598,756	6,572,082	8,749,421	195,447	601,701	766,142
	9022	8,523,082	24,519,762	11,819,973	25,785,609	45,310,962	16,284,170	4,272,399
Switz.	9018					60,728	53,571	2,997,887
	9019							
	9020							
	9021					2,504,229	574	345,193
	9022							146,835
India	9018					15,248	150,474	19,305
	9019							
	9020							
	9021							4,856

[50] Source: Individual country and trading block statistics: Comtrade

	9022					9,497		36,277
USA	9018					619,071	8,045,058	6,539,860
	9019				30,600	418,104	694,169	553,701
	9020					3,254	365,427	3,711,578
	9021						1,030,837	343,125
	9022				306,815	65,399	1,515,838	7,221,113
Japan	9018				550,488	75,703	119,818	1,020,433
	9019						129,735	461,706
	9020							
	9021							
	9022					7,586,974	88,161	2,318,398
Russian Fed	9018				1,429			2,551
	9019							
	9020							
	9021							
	9022							8,735
China	9018				169	69,653	136,275	1,485,340
	9019							31,008
	9020							600
	9021							11,613
	9022					9,211		1,947,213
Pakistan	9018							1,232
	9019							
	9020							
	9021							
	9022							
Turkey	9018					394,051	1,820,727	1,928,863
	9019					38,458	226,147	315,939
	9020					12609		34,715
	9021					2403	759,561	353,129
	9022					18,126	1,310	795,633
Totals	9018	30,870,620	32,429,721	96,659,992	104,800,666	81,425,258	44,510,851	63,443,139
	9019	801,338	1,105,497	4,622,138	13,659,031	4,427,086	3,729,470	2,547,940
	9020	0	285,569	0	104,166	41,752	372,695	3,845,769
	9021	2,044,125	2,598,756	6,572,082	10,129,039	2,886,616	4,080,575	2,420,256
	9022	8,523,082	24,519,762	11,819,973	26,250,775	53,197,353	18,300,279	17,055,254
Total of totals						141,978,065	70,993,870	89,312,358

Graph 5.2 Sources of medical appliance and device imports into Iraq 2005



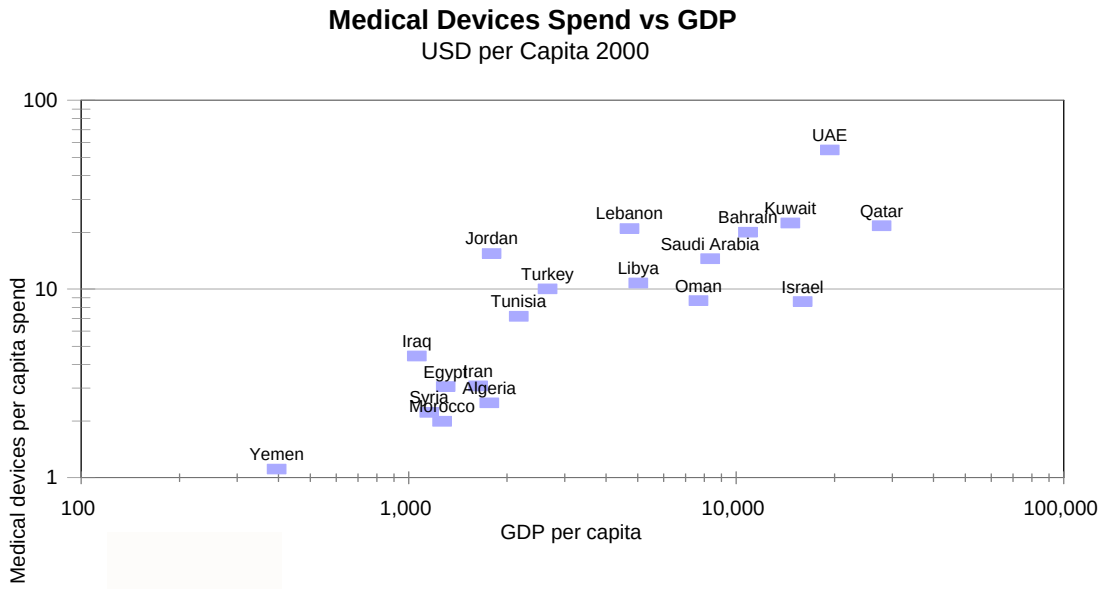
5.2.1 Comparative Market Size

Table 5.2.1 sets out the regional spend on medical products.

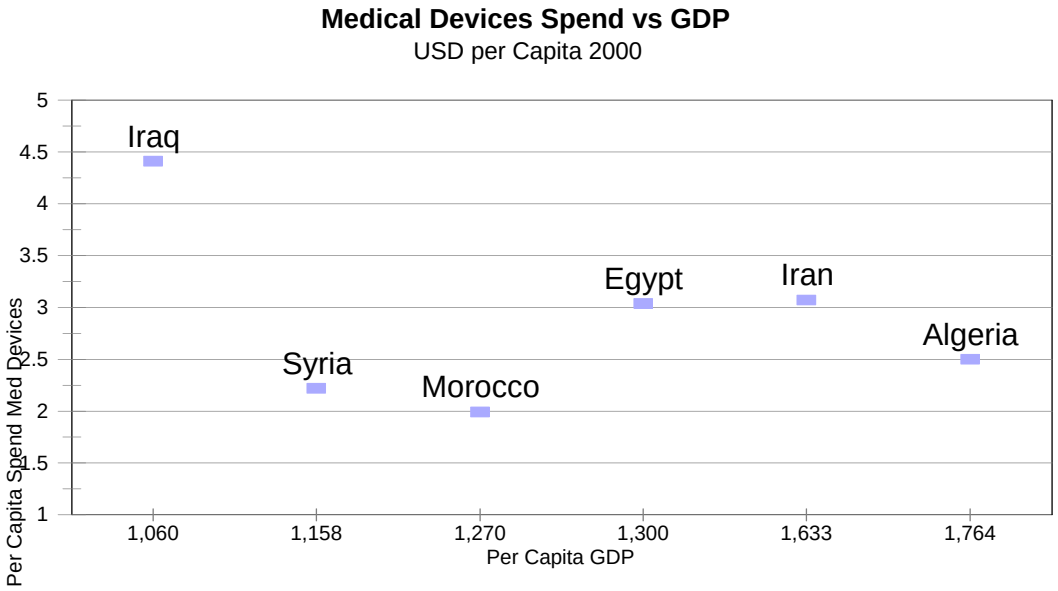
Table 5.2.1 Iraq Comparative Market Size and Potential Market Value; medical products 2000

Country	GDP/capita (USD)	Med dev spend/capita (USD)
Yemen	397	1.11
Iraq	1,060	4.41
Syria	1,158	2.22
Morocco	1,270	1.99
Egypt	1,300	3.04
Iran	1,633	3.07
Algeria	1,764	2.50
Jordan	1,794	15.42
Tunisia	2,170	7.16
Turkey	2,660	10.01
Lebanon	4,734	20.94
Libya	5,031	10.77
Oman	7,672	8.69
Saudi Arabia	8,355	14.47
Bahrain	10,874	20.00
Kuwait	14,672	22.38
Israel	15,985	8.59
UAE	19,393	54.48
Qatar	27,918	21.67

Graph 5.2.1(a) Iraqi market in comparison to other MENA countries



Graph 5.2.1(b) Iraq in comparison to neighbouring markets



5.2.2 Medical Products by Sub-Sector

The Iraqi medical device market is set out in table 5.2.2. This gives a value for imports in 2000, and then an estimate for the size of the market, by sub-sector in 2003 and a forecast estimate as to the value of the market in 2008. This was estimated on the 'AAGR' i.e., growth rate of 5.4% by the cited authors.

Table 5.2.2 Iraq medical device market by sub-sector[51]

	2000	2003	2008
Medical Device Market			
Domestic Production	n.a.		
Imports (USD mill)	97		
Exports (USD mill)	0		
Imports as % of market (est.)	n.a.		
Major Domestic Mfrs			
Projected Medical Device Market			
Market (USD mill)		63	80
AAGR %		5.4	5.4
Per capita (USD		2.9	5.4
By sector (USD Millions)			
Bandages and other medical supplies		5	7
Medical X-ray film		2	2
Rubber surgical gloves		2	2

[51] World Medical Market Report 2003; Espicom Business Intelligence March 2003

Medical, surgical or laboratory sterilisers		<1	<1
Wheelchairs		1	1
Contact lenses		2	2
Medical equipment		31	40
Electro-medical		7	9
Syringes, needles & appliances		8	10
Dental instruments and appliances		1	2
Ophthalmic instruments and appliances		1	1
Other instruments and appliances		14	18
Therapy apparatus		3	4
Orthopaedic/prosthetics goods		11	13
X-ray apparatus		7	9
Medical furniture		1	1

5.2.3 Conclusion

Given the lack of domestic manufacture, there is a significant opportunity for a domestic import substitution manufacturing opportunity. This will obviously rely on competencies and expertises, not explored in this report, but should not be discounted.

6.0 MEANS OF PHARMACEUTICALS AND MEDICAL PRODUCTS DELIVERY

6.1 Introduction

As noted in the introduction to this document the pharmaceutical and medical product sector is characterised by the nature of the command economy structure of the Iraqi economy. Prior to the invasion the Ministry of Health, through its wholly owned organisation 'Kimadia' was responsible for the purchase of pharmaceuticals and medical products, their distribution throughout the entire public health service network, and indeed sold product on to the private sector. A small private pharmacy sector developed after 1994, however this is small in volume terms, though possibly quite profitable where the pharmacy sells subsidised product to the retail customer. Most medical products as defined in Section 5 are managed solely through the public network, however some orthopaedic aids, for example wheelchairs, for which there is unfortunately a broad need, may be purchased in the market.

This chapter gives the role and functions of the Ministry of Health and its departments, then moves on to discuss procurement in the public sector, followed by the private sector, and then prescription and retail pharmacy.

6.2 The Public Sector

6.2.1 The Ministry of Health (MoH)[52]

The Health Ministry (MoH) was created in its current form in the middle of the 20th century. Its defined task is to provide health and medical services to all Iraqi citizens in normal and emergency circumstances. The Ministry also administers the health and medical centres of Iraq, and has a duty to provide best care to all.

The Ministry has developed health care within Iraq, expanding hospital, consultative and healthcare facilities in spite of the various conflicts and resultant damage inflicted over the last several decades.

6.2.2 Directorates and Facilities of Health Ministry

6.2.2.1 Minister's Office

The Minister's office administrates and organizes the Ministry's affairs and Minister's work program. This office also facilitates, in co-operation with the Information Department, meetings between the Minister with the media, and with private citizens.

[52] The following paragraphs were extracted and modified from the Ministry of Health website (www.healthiraq.org) and added to and adapted from other sources as required. It is acknowledged that some transliteration, or interpretation, may have slightly distorted the intent of the original text, this is without intention, and the text is designed to give the reader guidance.

The Institute of Forensic Medicine reports directly to the Minister's Office.

6.2.2.2 Minister's Deputy of Administrative Affairs

The Minister's Deputy has a private office assisting him with his duties; in particular this office also follows up the administrative plan and its implementation in cooperation with the other directorates of the ministry.

6.2.2.3 Ministry's Deputy of Technical Affairs

The Ministry's Deputy for Technical Affairs has a private office which is responsible for any technical implementation and evaluation of health services throughout the health service including the health centres.

6.2.2.4 Office of the National Consultant for Mental Health

This office was founded after April 2003. Its task is to raise the performance and efficiency of the psychiatric health services within the context of the current situation in Iraq to tackle personal crisis arising from it.

6.2.2.5 Legal Consultant's Office

The Legal Consultant's Office was founded after April 20043. The role of the Office is to broadly restudy health legislation, and to submit legal counsel for cases to the Ministry. These include MoH case, those from other Directorates within the Ministry, and the Directorates in the Governorates.

It also is responsible for checking all previous contracts under the 'oil for food program'.

It is tasked with restudying the invitations for contracts and bids, and is to submit draft regulations and laws to the state council related to the private sector.

6.2.2.6 Ministry's Office

The Office comprises the following departments:

International Health Department: Negotiates bilateral and multilateral agreements; implementation of agreements with WHO and the International Organization for Migration (IOM) and others; organising overseas treatment for patients; overseas training of MoH employees and foreign expert visits for treatment and training.

Information Technology Centre: Provision of ICT within the MoH, the Health Directorates and healthcare facilities including computers and accessories; provision of web services; co-operation on ICT projects with external bodies; networking all healthcare facilities provision and management of appropriate software; creation of an electronic library and providing user-friendly access; provision of centralised ICT services; creation and maintenance of a health-care statistical database.

Printing Department: Provision of printing services to MoH and all healthcare facilities; posters, bulletins and publications in co-operation with Information Department and Health Education Department; provision of external revenue generating printing services; establishing new printing facilities and re-training accordingly.

Information Department: Press relations; press releases; interviews with Health Minister, DGs; developing Journal of Health and Health Magazine; preparation of health education material on the risks of addiction; preparation of broadcast material including a weekly health programme, documentary material on the achievements of the MoH; information programme materials on current health situation; provision of materials for the web site; maintaining and developing a library of resources; market research to evaluate MoH performance; promoting public relations activities and a department in the Health Directorates, the Governorates, training the staff and supervising their performance.

Follow-Up Department: Communicating centrally originated instructions from MoH or other government bodies, to all MoH Directorates; monitoring their implementation; dissemination of instructions and decisions of the Minister the periodical meetings of the DGs and the Health Directorates; follow-up of urgent applications for drugs or equipment ensuring these are communicated to the appropriate authority by the most efficient means.

This office has several sections. It implements the following tasks:

1 - Following-up and executing instructions issued by high level authorities.
2 - Arranging agreements with friendly states.
3 - Giving opportunities for treatment patients abroad.
4 - Providing printing requirements, issue prints and publications.
5 - Information covering of health activities.
6 - Securing nets and electronic sites to the ministry and its facilities in addition to maintain computers.

6.2.2.7 General Inspector's Office

The role of the office is to improve the performance of all the public sector health institutions, audit the same and investigate public complaints. In addition it has a role in the supervision of the private sector. Ten teams of six members (medical, admin, financial etc) each have been formed to define the problems and issues facing the Health Offices as a prelude to their resolution. The office is also responsible for the management of public sector healthcare employee claims against the department.

In the private sector two employees from private hospitals, two pharmacies closed two private drug warehouses suspended for two months and respectively the employees concerned have been prosecuted and sentenced for drug trafficking. (2004)

6.2.2.8 Legal, Financial and Administrative Directorate

The roles of the Directorate include the human resources function; accounting and finance; legal and counselling functions, including investigatory functions; facilities management and transportation. Provision of crèche facilities. The Directorate comprises the following Departments:

- Department of Personnel
- Department of Accounting
- Department of Legal Affairs
- Department of Administrative Affairs

6.2.2.9 Directorate of Medical Operations and Specialized Services

Founded after the April 2003 its role was to transfer military medical treatment from the Ministry of Defence to MoH. Subsequently its role has since expanded to include supervision of the ambulance service; emergency medicine; disaster control; management of specific medical categories; e.g., the armed forces, disabled; special needs; the prisons, airports and aviation. This includes provision of emergency medical supplies, when required.

The following rehabilitation centres have been established within the health-care structure in Baghdad and the Governorates to provide medical services for rehabilitation of the disabled:

- Al-Salam disabled rehabilitation centre
- Al-Musel disabled rehabilitation centre
- Thi-Qar disabled rehabilitation centre
- Al-Ghadeer disabled rehabilitation centre
- Al-Basra disabled rehabilitation centre
- Al-Hamza disabled rehabilitation centre
- Babylon disabled rehabilitation centre
- Baghdad artificial limbs centre
- Al-Anbar disabled rehabilitation centre
- Karkuk disabled rehabilitation centre
- Al-Thor city specialist health clinic
- Al-Shomookh City specialist health clinic

The above centres, co-ordinate with the non-governmental humanitarian organizations:

- to rehabilitate/rebuild health institutions
- to provide medical services and disabled rehabilitation
- to re-organize the National Assembly for Rehabilitation
- to coordinate with the National Assembly for Minor Affairs through a joint Minors Victim Care Programme

Recently MoH has formulated the following facility within the Prisons of Iraq Rehabilitation Office/Ministry of Justice. These institutions provide the medical & health services for rehabilitating prisoners with medicine and vaccines free of charge:

- the health centre of Al-Resafa car and bus depot
- the medical clinic of Kadhmya Awal Prison
- the medical clinic of Al-Rahmanya Prison for Juveniles

A memorandum of understanding has been signed with the MoH and the Iraqi Army for providing the Army with contracted medical and management staff from MoH for four years. Health centres for the army have been established for treating, examining and evacuating members of the armed forces and their families:

- Al-Taji Centre
- Karkoush Centre
- Al-Kasak Centre

Selective centres in Baghdad/Mousel/Basrah have been established for examining volunteers for the army.

To provide medical treatment to the police and army, and emergency treatment to the public, Al-Amin specialised medical clinics have been established in Al-Ressafa and Al-Karkh.

A National Guard medical clinic has been established and is supervised by the Medical Operation & Specialized Services Office in Baghdad to provide the military staff with medical care treatment, and emergency medical and surgical teams are provided to cover terrorist activity.

6.2.2.10 Directorate of Planning and Resource Development

Its roles are the implementation of MoH strategic plans and health policies and budgeting. It also supervises the distribution of technical, health and medical professions to MoH facilities. It also evaluates the delivery of healthcare services, identifying areas of failure, problems and issues in order to resolve these, advising on organisational issues within the MoH and its Directorates.

The tasks of the Directorate (abbreviated) include the following:

1. Reformation of the operation of the health facilities
2. Support for decentralised functions in crisis management
3. Human resources training function; including medical, technical and administrative, domestically and overseas
4. Research according to the needs of MoH and national and international developments
5. Providing administrative support for library creation
6. Developing Continuous Professional Development (CPD) programmes
7. Development of on-line teaching facilities
8. Development of regulations for the practice of nursing and midwifery
9. Raising the standard of nurse training
10. Reducing the length of nurse training
11. Improve the efficiency of data collection and compilation and statistical analysis within the health service
12. Maintaining medical and human resources within the governorates and districts
13. Construction of a central database through the internet
14. Co-ordination with the Ministry of Higher Education and Scientific Research for the provision of advanced studies in line with the needs of the MoH
15. Achieving the maximum benefit from the available financial resources from the budgets of the Directorates, or other external resources (donors, NGOs, etc.) as they become available
16. Monitoring and evaluation of implementation of the health strategy training and development

6.2.2.11 Directorate of Technical Affairs

The Directorate supervises the operations of state and private health facilities. It also sets the conditions for licenses, licenses and registers new pharmacies and laboratories. The Directorate determines the need for and the quantities of pharmaceuticals and medical appliances that may be sold to or by them.

It establishes committees to evaluate disease status.

It comprises the following departments:

Registration Department: responsible for the documentation, and registration of health-care companies and pharmacies

Curative (Clinical) Department: supervises the operations of the curative (clinical) department, health and family planning clinics, private and public, inherited diseases, notably anaemia; supervision of distribution, and redistribution of medical equipment.

Advisory Committee Department: Submits advice on clinical practice, preventive medicine, and laboratory services; is responsible for medical equipment distribution; advises on pharmaceutical distribution and deficiencies, and evaluates research and studies in health-care facilities.

Laboratories Department: Supervises laboratories providing its own services and private establishments, monitoring performance. Co-ordinates with the import committees needs assessment for medical equipment and their distribution. Supervises the quality control programmes and assists in restoring standards in deficient laboratories.

Medical Committees Department: Acts as guardian to incompetent individuals; establishes specialist medical committees to review cases and makes recommendations for treatment overseas.

Pharmacy Department: Supervises and evaluates pharmacy services in health care establishments, controls the import, distribution and use of drugs in the public and private sector.

Department of Herbal Medicine: Promotes the benefits and uses of medicinal herbs in primary health care; explains risks of random use; maintains and advertises the list of internationally recognised safe herbs; establishes specifications as to type, dose and cautionary notes; co-ordination with other government departments to promote the herbal medicines industry.

Department of Oral Health and Dentistry: Technical supervision of clinical practice; prevention of oral and dental disease; population surveys of dental and oral health; securing medical, technical and support staff in the sector in co-operation with Directorate of Planning and Resources, and the WHO; import of dental equipment and instruments in co-ordination with the appropriate Departments.

6.2.2.12 Directorate of Projects & Engineering Services

This is a newly established directorate, formerly the Department of Buildings Planning, its main task is to build and rehabilitate health facilities which belong to the MoH. It is also responsible for developing, evaluating and following-up reconstruction works implemented by the Ministry, NGOs and others from overseas donors throughout Iraq, and as required, the direct implementation of small and large projects belonging directly to the Directorates of the Ministry.

6.2.2.13 Directorate of Public Health and Primary Health Care

This Directorate was founded at the inception of the MoH. Its role is in preventive medicine, supervising the provision of food, medicines, immunisation, and health awareness with the aim of creating a healthy environment for all, in conjunction with the other MoH Directorates, other government and non-governmental facilities.

6.2.2.14 General Company for Marketing Medicines and Medical Appliances

This directorate, also known as the State Company for the Importation and Distribution of Drugs and Medical Appliances, trades as Kimadia and until 1994 was the sole body allowed to import, market and distribute drugs sera, vaccines, scientific and medical appliances and equipment and services. The company is the sole importer to the public sector. It also arranges contracts and agreements both inside and outside Iraq and opens stores and branches to the medicine information bureau inside and outside the country in order to achieve its targets. See section 5.4.2 on procurement.

The company's development plan included (for 2005) (abbreviated):

1. provision, storage and distribution of drugs and medical supplies
2. maintenance & service of medical equipment in all health directorates
3. training of technical, engineering and medical staff of the company
4. using price control mechanisms to reduce costs to consumer and pharmacy
5. co-ordinate and encourage domestic production
6. computerisation of all activities including more effective inventory management
7. increase and improve communication technology, including e-mail, tender and bid promotion using the web to achieve greater participation and competition to achieve keener pricing. In addition, increase understanding of modern drug development technology and medical appliances

6.2.2.15 Directorate of Popular Medical Clinics

This Directorate administrates the popular medical clinics and evening health insurance clinics. It is also responsible for the provision of all requirements to ensure health services to the populace without charge, including providing medicines not available in the local market, and those for chronic diseases.

6.2.2.16 Directorate of Medical City

This Directorate supports the medical specialities in various hospitals and centres with the aim of rehabilitating clinics and providing up to date equipment to examine and treat patients at low cost.

6.2.2.17 Health Directorates of Baghdad and the Governorates

These are the functional and operational boards which manage the public health sector by Governorate.

6.3 Procurement in the Public Sector

6.3.1. Introduction

Within the public sector the Ministry of Health (MoH), through its directorates, is responsible for the procurement and supply of all pharmaceutical and medical products, consumables and similar to the public sector, including the public and specialist hospitals and the care clinics. The MoH maintains a list of approximately 2,500 pharmaceutical items which are divided into the following categories:

- Chronic diseases

- Antibiotics
- Hormones
- Vaccines
- Others

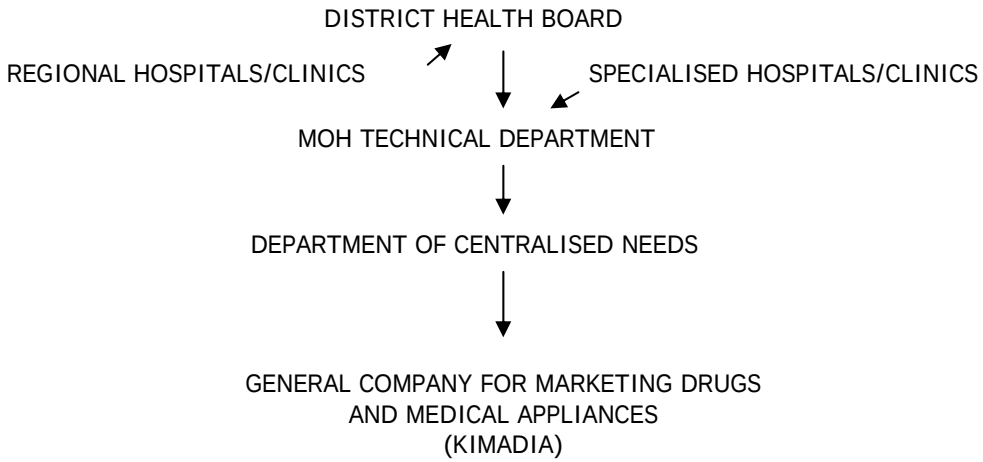
In principal the government and hospitals only look to the supply of antibiotics, hormones, vaccines; the private sector has input into analgesics, anti-cough syrups, OTC products etc.

Pharmaceuticals are provided through mixture of imports and domestic production.

6.3.2 The Procurement Process[53]

Each governorate (province) has a nominated centre, the District Health Board, normally in one of the principal hospitals, where requirements for the following year for that governorate are collected, co-ordinated and collated. A single submission is then prepared and submitted to Baghdad.

Diagramme 6.3.2 Relationships in the first stages of the procurement process



The submission is made to the MoH Technical Department who then appraises the submission, looking for example for requests for obsolete drugs, the potential to substitute newer, or more efficacious, treatment (s). A variety of committees are involved in this process and then a lists for pharmaceutical products and equipment are prepared. Once this stage is reached the lists are passed to the 'Department of Centralised Needs' where quantitative elements of requirements are prepared. A statistical appraisal (in theory) is made on the basis of known factors, e.g., population, disease prevalence etc., this includes a discount factor applied on the basis that it is believed that each health district over estimates its requirements for the forthcoming year.

The specialist hospitals submit their own requirements which are then evaluated separately.

The lists are then evaluated for:

[53] Sources: Private communication; Presentation by Dr Firas Hilmi, Al-Assad Group of Companies, July 2005, UNDG/WB Working Group paper 'Medicines and Medical Supplies', undated arising from paragraph 2.15 of 'Health' Working Paper of UN/World Bank October 2003. David Nabarro WHO./'Information' Ministry of Health website: www.healthiraq.org/English/home/htm

- domestic availability
- quantity against availability
- quality of imports and (versus) domestic production
- price

Tenders are then issued by the General Company for Marketing Drugs and Medical Appliances[54] ('GMC' herein) – a wholly owned operating company of the MoH, trading as Kimadia, a directorate of the Ministry of Health (MoH). There are two large tenders each year of 1,000 + items, in addition to smaller tenders for individual hospitals or governorates. All tenders are placed on the page at www.kim-moh.net.

There will be restricted tenders for specialist supplies, for regular 'contract' suppliers and then public tenders will be published (including on the internet) for common supplies. All those tendering must be an authorised tenderer.

TENDER IS ISSUED (KIMADIA)

↓

WWW.KIM-MOH.NET

↓

AUTHORISED TENDERER

↓

SUBMIT A TENDER

Tenders are received and evaluated and purchase orders made.

Evaluation is conducted by technical or consultant committees, they will decide on the best 3-5 offers. These will then be passed to the Import Committee of Kimadia who will then determine the supplier by requesting and comparing what additional benefits, e.g., discounts, training, etc. that the tendered might offer. The Import Committee's decision is then passed to the Ministerial Purchasing Committee who will then approve, reject or modify additional requests.

The final decision is passed back to the DG of Kimadia, who will instruct that a contract be issued. This latter will be shown to the company's representative for approval and then passed to the Kimadia department responsible for the issue of letters of credit (LC). When funds are available the contract is issued and passed to the contractor for signature. The LC is then released.

As the orders are received they go to the Kimadia distribution depots (see 6.3.3), where samples from each batch are sent to the National Quality Control Laboratories (NQCL) for technical evaluation. Penalties against the contract are exacted if the quality is not within criteria, or cancelled if sufficiently reduced. If the delivery is approved then Kimadia will start distributing on a proportional basis to all District Boards that requested that item.

[54] Also known as the State Company for Importation and Distribution of Drugs and Medical Appliances' trading under the name 'Kimadia'.

6.3.2.1 Becoming a Recognised Supplier/Submitting a Tender[55]

6.3.2.1.1 *Manufacturer*

A manufacturer (and supplier) should submit a letter of authorisation that states:

- the speciality of the company
- the name an Iraqi 'scientific bureau[56]
- the name of a pharmacist licensed by the Iraqi syndicate of pharmacists as a sole and exclusive representative

The letter of authorisation should be 'legalised' (counter-stamped) by:

- The Chamber of Commerce in the country of origin
- Ministry of Foreign Affairs in the country of origin
- Iraqi Embassy or Representative in the country of origin

6.3.2.1.2 *Supplier*

A supplier, in addition to the requirements of 6.3.2.1.1 should also provide the following:

- names and specialities of the companies represented
- a letter from the manufacturing company authorising you to represent them, 'legalised' as above

You must have sole and exclusive rights to represent that manufacturer in the territory of Iraq for all of its products, and the letter (above) must state that.

6.3.2.2 Domestic Preference

As in most closed economies the government operates a policy for preferential treatment of domestic suppliers. In this instance the government will pay an (approximate) 20% margin over the imported price for a specific product[57] if it is available, or can be made available, from domestic manufacture.

6.3.3 Pharmaceutical Distribution

The greater part of pharmaceutical distribution in Iraq is conducted by Kimadia. A full preliminary assessment of the Kimadia system is given in Appendix E[58]. The organisation was founded in 1966 and is by repute a highly centralised and fairly secretive organisation. It comprises a distribution network of some 7,500 public, semi-public and private central, governorate and district warehouses and distribution centres.

Up until 1994 it was the sole body authorised to distribute medicines, to both the private and the public sector.

[55] Presentation by Dr Firas Hilmi, Al-Assad Group of Companies, July 2005
[56] A recognised pharmaceutical importer
[57] Personal communication, exemployee of Kimadia, qualified pharmacist
[58] Situational Analysis Report for Kimadia: Iraq Health System Strengthening, Abt Associates Inc 11 July 2003 for USAID

It was proposed that Kimadia be privatised in the autumn of 2003, however these plans were suspended, and is believed by the author to be operating in its traditional capacity.

Because of the nature of the procurement system and inefficiencies within it, there are shortages of some, if not most, products and occasionally drugs are distributed past their expiry date, all of which is blamed on Kimadia.

6.4 Procurement in the Private Sector

In the private sector the importers are the 'Scientific Bureau', most of whom are acting as agents or representatives of overseas manufacturers or manufacturers agents. They make their purchases and either directly, or through the Kimadia distribution network imports go to the wholesalers and to the retail pharmacist, or to the private healthcare institution. Diagramme 6.5.1 shows the distribution of medicines into the private retail market.

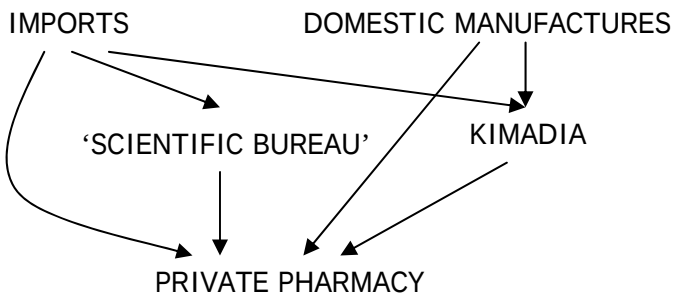
6.5 Prescription, Dispensing and Distribution of Medicines

6.5.1 The Pharmacy Licence

The pharmacy licence costs ID 70,000 per month which it is understood can further exchange hands on the black market for up to 2,000,000 ID. The person making an application for the licence has to be a qualified pharmacist. A single pharmacist may have a chain of pharmacies.

Within the Iraqi health system there are a set of drugs that can only be dispensed by prescription. A list of these drugs is displayed in every pharmacy, both public and private. This list corresponds to the list of controlled substances found in most Western countries, e.g., alkaloids, substances prone to abuse etc. On presentation of the prescription in the public pharmacy the products are dispensed, if available for a single fee of ID250, or in some special circumstances ID500. (In the private pharmacy, the current price of the dispensed product would be charged, noteworthily in the case of imported specialist products).If a specific medicine for less common conditions is prescribed, the pharmacist will order this in from the distributor – mainly Kimadia. If the medicine is for a chronic condition not available on prescription the pharmacist will again buy in the product for the individual.

Diagramme 6.5.1 Pharmaceutical distribution chain into the private retail market



Common medicines (over the counter, OTC) since 2003 are found in the market place, as are prescription medicines. Until the restoration of a formal regulatory environment this situation is likely to continue for the foreseeable future.

The prescribing doctor will frequently, if not always, identify the pharmacist that the patient should go to for his medicine, and that they have a business relationship. The historical precedence of this is unknown, but it is widely believed, certainly amongst some communities, that this is of some standing. When purchasing a medicine the selection criteria is the brand and then the price (if for self-medication), for example, notwithstanding the large volume of Jordanian products within the market place there is a stated preference for European brands, and Iraqi brands are respected for their perceived quality and low prices.

6.5.1.1 Current Conditions

It appears that the system of control of the pharmaceutical distribution chain has collapsed (to a greater or lesser extent). It is widely reported[59] that pharmaceuticals are available 'on the street' i.e., in most of the main markets. Many of these products are obtained from MoH licensed pharmacies, both in the hospitals and clinics and the independent sector. In addition there is a significant trade in illicit imports. Considerable concern is expressed over this trade, because apart from flouting regulations the standard of the products so obtained is debatable. It is also apparent that quantities are sold illegally from the MoH stock holders and licensed pharmacies to the street traders at favourable prices. The MoH intends to tackle this practice, however acknowledges corruption within its own ranks, with drugs being supplied directly from the Ministry.

Obviously this trade is encouraged by popular demand, and is, however, exacerbated by an increasing shortage of trained pharmacists within the community – exacerbated by the current security situation, which includes the targeting of many professional groups including pharmacists. This is compounded with the closure of several teaching institutions60, shortage (loss, theft and effect of sanctions) of equipment, access to scientific literature, with consequential impact on the healthcare system.

In addition there has been an increasing willingness of licensed pharmacists to dispense proscribed, or restricted, medications to addicts and drug abusers, much misuse or inappropriate use of antibiotics, the latter of which will undoubtedly have long-term detrimental potential for healthcare in the country. It is noted that non-compliance with demand for illegal dispensing, or attempts to control the supply of medicines can be, and often is, met with violent assault or assassination.

The consequences are a significant shortage of essential medicines, antibiotics in particular, treatments for chronic conditions, e.g. diabetes, c.v. disease, and others. In addition it is claimed that 97% of medicines are of unknown origin.

6.6 Pharmaceutical Promotion

There is no pharmaceutical promotional activity as recognised in the West. Detailing is unknown. It appears that the only means of encouraging the use of one brand over

[59] Sources: various: including Iraq Directory interview with Dr Mustafa Ali www.iraqdirectory.com, interviews with Dr Ayad Ali, reported by Pamela Mason in Tomorrow's Pharmacist (January 2005)and The Pharmaceutical Journal, 274: pp115-629 Jan 29 2005 www.pjonline.com and private communications

[60] Including the Universities of Mosul and Anbar.

another is to understand the nature of the additional benefit that needs to be delivered to the MoH, or the influencing of individual specialists where they are able to specify specific product. However where the state purchases there is no apparent means of influence.

6.7 Medical Products, Appliances and the Like, Procurement and Dispensing

Kimadia is responsible for the purchase and distribution of products within the public sector, the private sector however does act as a source of supply for orthopaedic aids such as wheelchairs, crutches etc. So much so that where the private sector supplies the public sector won't.

6.8 Kimadia Improvement and Enhancement Programme

There is a US Government funded initiative about to be launched that is to address many of the issues raised in this document, and make appropriate recommendations for the reform of the Kimadia organisation, and ultimately to their implementation.

7.0 RISKS AND ISSUES

7.1 TRIPS

One factor that needs to be explored is the impact of WTO accession discussions on the domestic pharmaceutical manufacturing base.

Pharmaceutical manufacture in the Near and Middle East is characterised by the production of generics, the reformulation of active pharmaceutical ingredients, and blatant imitation. On the application of Jordan and Egypt to the WTO, for example, the obligations under the TRIPS element of the Agreement had to be enforced. In the case of Jordan of the fourteen pharmaceutical companies that existed only four currently operate to a significant extent. Co-incidentally these were the original manufacturers and had established themselves in the domestic and regional markets. The other companies had moved into the manufacture of pharmaceuticals, particularly in the generic and imitation market as they saw the profitability of the sector. However, following Jordan's accession to the WTO, and the decision of the Jordanian Government to fully implement the TRIPS agreement much of the business of these latter companies fell away.

In the case of Egypt, the specific exclusion of pharmaceuticals (along with foodstuffs) from product patentability[61] was a major lobbying point amongst the US industry prior to Egypt's accession to the WTO. The US industry argument was that adoption of formal patent recognition and protection would enable an environment to foster investment, technology transfer, research and development to encourage the growth of the domestic industry. However a substantial industry established itself in Egypt, albeit by the production of generics, imitation and reformulation of patented products with the establishment of some 40 manufacturing companies (that figure includes multi-nationals) domestically. The non-acceptance of patent law was seen as protectionism for the nascent pharmaceutical industry that relied on the copying, or breaking the patent, or reverse-engineering, reformulating, patented drugs. Egypt also developed a successful (and increasing) export market. However, following the accession to the WTO and the passing of TRIPS compliant legislation, which allowed a transition period to the end of 2004, with pipe-line protection the industry has not suffered as much as was feared. Subsequently the country has benefited from substantial inward investment with, for example, the establishment of a new manufacturing facility by AstraZeneca this year worth some USD 32 million. A more detailed discussion of TRIPS legislation applied to Egypt is given by the Egyptian Initiative for Personal Rights[62].

Within Iraq the original Patent and Industrial Specimens Act No 65 was enacted in 1970. This was subsequently amended and published in the Official Gazette in September 1999[63]. These amendments made it possible to register patents for pharmaceutical and medicinal preparations, and established the patent period as twenty years (ten years renewable in two instalments of five years) However this was again subsequently amended under CPA order # 81 April 2004, to provide full patent protection. At the time of

[61] Submission of the Pharmaceutical Research and Manufacturers of America (PhRMA) for the National Trade Estimate Report on Foreign Trade Barriers (NTE) 2000. Dec 3 1999. Consumer Project on Technology. www.cptech.org

[62] Egyptian Initiative for Personal Rights. 8. Patent protection in Egypt. www.eipr.org/en/reports/trips05/enstud11.htm

[63] SABA Bulletin November 2000

writing the law is being revised and updated to include full compliance with WTO TRIPS requirements. The main issue is not the legal status of patent protection; it is (will be) the enforcement of such law.

7.2 Tenders and Contracts

As described in this document, the process through which non-domestic suppliers bid for tender, though apparently transparent, is open to abuse, for example in the manner of obtaining 'authorised tenderer'. It is also very open to individual and institutional rent-seeking. This is particularly apparent in the bidding process where concepts such as 'additional benefit' are left to a degree unexplained. For accession this procedure will have to be simplified and become more open.

7.3 Pricing, Price Control, and Price Differential

A significant issue is the differential pricing for domestic suppliers, which acts as a state subsidy and is an anti-competitive practice. Though it is undoubted that Iraq would be allowed a transition period before full compliance, this has to be addressed.

7.4 Other Issues

7.4.1 GMP

For Iraqi products, or producers to become attractive to legitimate external investors it will be necessary to ensure compliance with GMP standards. This will consist of a number of elements; for example, training manufacturers in GM practice, training the MoH inspectors in modern practice and inspection techniques, staffing and maintaining the inspection teams, and, in addition, when a company wishes to export, external (non-Iraqi, perhaps UK, EU or FDA) teams to inspect.

7.4.2 Illicit Supply

One area of significant concern within Iraq is the illicit supply of pharmaceuticals/medicines both as contraband, counterfeit and of dubious (and frequently unknown) origin. Appropriate policing (including customs and border controls) mechanisms need to be put in place to protect the rights of the manufacturer, maintain reputation, and protect the populace.

7.4.3 Distribution and Logistics

These are currently (for legitimate supply) effectively entirely in the hands of the MoH and its subsidiary 'Kimadia', thus creating a state monopoly. Also given that 'Kimadia' restricts the supply of drugs and makes the choices over distribution the system again is open to rent seeking, both at the personal and institutional level.

7.5 SWOT

Strengths

- Active manufacturing – public, private and illegal
- Strong market demand
- Active government procurement
- Entrepreneurial culture developing

Weaknesses

- Monopsony purchases
- Unregulated market sales (secondary/black/grey), of illegal imports, inadequately controlled domestic production, ineffective and sub-standard products
- Lack of regulatory enforcement of standards for GMP, GLP
- Pharmaceutical sales, product sourcing, patent protection etc
- Bureaucratic
- Price controls
- Differential pricing regimen
- Economic uncertainty
- Low per capita consumption
- Government contracts unpredictable (only tendered when money available)
- Unreliable payment system
- Health care system in disarray
- Loss of healthcare professionals
- Shortage of qualified technical staff
- Sectarian issues

Opportunities

- Potential privatisation programme(s)
- As public sector finances improve, per capita expenditure will grow
- Major import substitution opportunity
- Opportunity to licence in products
- Opportunity to buy into local producers with technology transfer package
- Opportunity in niche sectors, e.g., phials, sterile products etc
- Undervalued assets
- Unused facilities
- Joint ventures
- Specialist Manufacturing – Long-term

Threats

- Security situation (personnel)
- Rent seeking (bribery, corruption, protection rackets etc)
- Security situation (property), threat of theft, looting, vandalism
- Lack of effective banking and cash management systems

8.0 CONCLUSIONS AND RECOMMENDATIONS

8.1 Conclusions

It is apparent from this study, and many others cited, that there are significant opportunities for investment in the Iraq pharmaceutical and medical products sectors.

However, as a result of many decades of operating under a command economy, and the last several decades of war, sanctions and internal strife a variety of measures need to be undertaken before a liberal market economy can exist in this sector.

It is understood that a government which wishes to create a public health system, underwritten by the state must have control of its own purchases; however there exist constraints within the system, as outlined in the document which allow opportunism and rent seeking.

This report was written with limited capacity to engage the Ministries and the domestic manufacturing sites, so there are inherent frailties within it. The recommendations are therefore prefaced with the need to conduct further research as conditions improve and circumstances permit.

The pre-requisite for investment in the state sector is the creation of appropriate privatisation and restructuring mechanisms. The Government of Iraq and its agencies may not wish for a variety of reasons to privatise in one move, however, structure must be developed that allow the opportunity for private-public partnership programmes (PPP), private funding initiatives (PFI) or similar constructs. The following recommendations outline some of the preliminary steps to be taken.

It is essential that reform of the state enterprises be undertaken to remove some of the gross inefficiencies that occur within the state sector, cross subsidisation, false pricing, embedded work practices, and in the pharmaceutical sector, non-compliance with GMP, though it is accepted that these aspects also exist within the private sector.

In addition the non-transparent price subsidisation of goods, through the MoH to both the public and private sector has to be reformed.

8.2 Recommendations

This study by its nature was primarily a desk study with interviews being carried out whenever possible due to the means and circumstances under which was conducted, with restrictions on access to the factories, both public and private, and to the Ministry of Health. This preliminary study should be revised when conditions permit access to actual performance statistics, the Ministry of Health and its operating subsidiaries.

It is apparent that the industry sectors considered are open to investment opportunity, however, the system constraints, explored in the body of the document, requires structural adjustment. Therefore, subsequent to the prime recommendation, the main recommendations of this report are of a policy and regulatory nature.

8.2.1 Formal definition of the nature, business and manufacturing assets of each of the state enterprises must be established.

8.2.2 The rules, regulations, by-laws by which a (private) entity may make an offer to supply goods and, or, services to the state sector should be revised.

8.2.3 The appropriate provision under extant company law for a company to freely compete in the new liberal market economy without prejudice or favour (to include the provisions that will be made under free market legislation) should be able to be applied under the Kimadia procurement system.

8.2.4 The proper registration of all businesses with appropriate deterrent and sanctions should be in effect.

8.2.5 The Ministry of Health should carry out, and is so enabled to carry out, its legal responsibility to ensure GMP and GLP, in each and every instance.

8.2.6 The MoH, and in particular, its' operating subsidiary known as Kimadia should be thoroughly restructured, to enable transparency in its dealings, and that its functions be restricted.

8.2.7 The system of licensing, approvals, and registration with its inherent opportunities for rent seeking should be reviewed and appropriate deterrent and sanction be introduced.

8.3 Private Sector Investment

There are a number of specific routes to private investment in the pharmaceutical sector in Iraq. These can be briefly summarised as:

An external supplier
An importer and distributor
A low value manufacturer
A high value manufacturer

Each of these may be evaluated separately; however, within the current system each of these has major constraints:

External supplier: Some major elements include competition with embedded contractors for major supplies; enabling proof of facility, i.e., to be sole contractor or agent for a manufacturer.

Private importer/distributor: Current conditions require complicity with pharmaceutical distributorships; most of these are already in the hands of a select few wholesalers/distributors, in addition the requirement for licensing provides a barrier to entry, and the opportunity for volume/margins is low as pricing of most products is mainly in the control of the MoH/Kimadia as their distribution is heavily subsidised.

Low value manufacturer: The main barriers to entry are the capital cost of establishing a business; the real main competitors are the low value

(unlicensed/illegal) manufacturers, the company still has to be licensed and authorised as a (legal) supplier. The opportunity to supply the private sector is small as commodity products are already produced in quantity. Opportunities for non-domestic players are small if not negligible.

High value manufacturer: Again barriers to entry include the high capital cost of establishing, and maintaining plant, the current domestic market is small, however this might be an option for the future.

In the short term, until the conditions set out in the recommendations are fulfilled there are few opportunities for external investors, except where these are government backed. In the long-term, with the additional support of the government funded research institutes there is a good prospective for the pharmaceutical industry in Iraq, albeit initially at the domestic level.

An initial approach is potentially for a long-term investment at the SME level. It is suggested this would have to be a joint venture with a current operator, for cash and technology, be that manufacturer come from the current private, or the re-structured public sector.