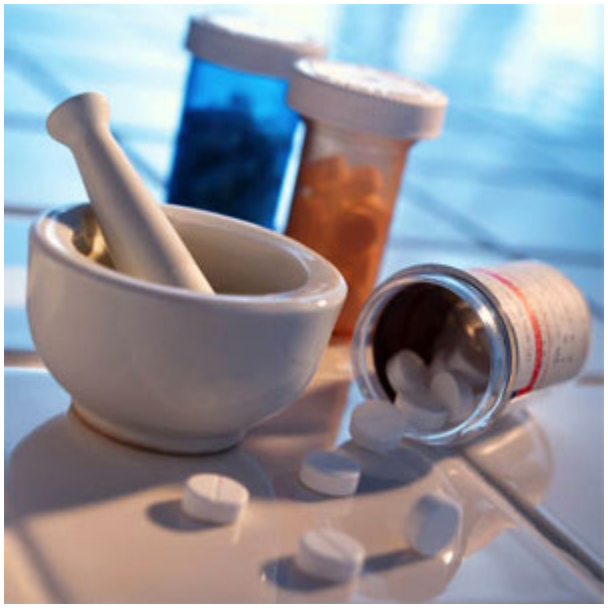
IRAQ

PHARMACEUTICAL COUNTRY PROFILE



Iraq Pharmaceutical Country Profile

Published by the Ministry of Health of the Republic of Iraq in collaboration with the World Health Organization

2011

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Foreword

The 2011 Pharmaceutical Country Profile for Iraq has been produced by the Ministry of Health, in collaboration with the World Health Organization.

This document contains information on existing socio-economic and health-related conditions, resources; as well as on regulatory structures, processes and outcomes relating to the pharmaceutical sector in Iraq. The compiled data comes from international sources (e.g. the World Health Statistics [1, 2]), surveys conducted in the previous years and country level information collected in 2011. The sources of data for each piece of information are presented in the tables that can be found at the end of this document.

On the behalf of the Ministry of Iraq, I wish to express my appreciation to Chief Pharmacist Jamila Z.Lafta / Head of pharmacy department, Pharmacist Sahar M.Mahdi, Pharmacist Noor N. Abdulla, Chief Pharmacist Qais J. Talib / Deputy DG/KIMADIA, Dr. Imad A. Abdulwahhab / Directorate of Planning, Dr. Sanaa S. Majeed / Directorate of Planning and Dr. Khalid R. Hasan / Directorate of Planning from Iraqi MOH for their contributions to the process of data collection and the development of this profile.

It is my hope that partners, researchers, policy-makers and all those who are interested in the Iraq pharmaceutical sector will find this profile a useful tool to aid their activities.

H.E. Minister of Health

Dr. Majeed Hamad Ameen

Date: February 2012

Table of content

Introduction

This Pharmaceutical Country Profile provides data on existing socio-economic and health-related conditions, resources, regulatory structures, processes and outcomes relating to the pharmaceutical sector of Iraq. The aim of this document is to compile all relevant, existing information on the pharmaceutical sector and make it available to the public in a user-friendly format. In 2010, the country profiles project was piloted in 13 countries (http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index.html). During 2011, the World Health Organization has supported all WHO Member States to develop similar comprehensive pharmaceutical country profiles.

The information is categorized in 9 sections, namely: (1) Health and Demographic data, (2) Health Services, (3) Policy Issues, (4) Medicines Trade and Production (5) Medicines Regulation, (6) Medicines Financing, (7) Pharmaceutical procurement and distribution, (8) Selection and rational use, and (9) Household data/access. The indicators have been divided into two categories, namely "core" (most important) and "supplementary" (useful if available). This narrative profile is based on data derived from both the core and supplementary indicators. The tables in the annexes also present all data collected for each of the indicators in the original survey form. For each piece of information, the year and source of the data are indicated; these have been used to build the references in the profile and are also indicated in the tables. If key national documents are available on-line, links have been provided to the source documents so that users can easily access these documents.

The selection of indicators for the profiles has involved all technical units working in the Essential Medicines Department of the World Health Organization (WHO), as well as experts from WHO Regional and Country Offices, Harvard Medical

School, Oswaldo Cruz Foundation (known as Fiocruz), University of Utrecht, the Austrian Federal Institute for Health Care and representatives from 13 pilot countries.

Data collection in all 193 member states has been conducted using a user-friendly electronic questionnaire that included a comprehensive instruction manual and glossary. Countries were requested not to conduct any additional surveys, but only to enter the results from previous surveys and to provide centrally available information. To facilitate the work of national counterparts, the questionnaires were pre-filled at WHO HQ using all publicly-available data and before being sent out to each country by the WHO Regional Office. A coordinator was nominated for each of the member states. The coordinator for Iraq was Pharmacist Jamila Z. Lafta.

The completed questionnaires were then used to generate individual country profiles. In order to do this in a structured and efficient manner, a text template was developed. Experts from member states took part in the development of the profile and, once the final document was ready, an officer from the Ministry of Health certified the quality of the information and gave formal permission to publish the profile on the WHO web site.

This profile will be regularly updated by the Ministry of Health of the Republic of Iraq. Comments, suggestions or corrections may be sent to:

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Section 1 - Health and Demographic Data

This section gives an overview of the demographics and health status of Iraq.

1.1 Demographics and Socioeconomic Indicators

The total population of Iraq in 2009 was 32,326,000 with an annual population growth rate of 3.4 %.[3,4] The annual GDP growth rate is 1.2 %.[5] The GDP per capita was US$ 2,036 (at the current exchange rate[i]).

43.1 % of the population is under 15 years of age, and 4.34% of the population is over 60 years of age. The urban population currently stands at 66.62% or the total population.[3] The fertility rate in Iraq is 4.9 births per woman.[5]

The adult literacy rate for the population over 15 years is 74%.

1.2 Mortality and Causes of Death

The life expectancy at birth is 69 and 74 years for men and women respectively. The infant mortality rate (i.e. children under 1 year) is 24/1,000 live births. For children under the age of 5, the mortality rate is 29.5/1,000 live births. The maternal mortality rate is 32/100,000 live births. [5]

[i] The exchange rate for calculation for NCU is 1 US dollar = 1,170 Iraqi Dinars (IDQ).

The top 10 diseases causing mortality in Iraq are

	Disease
1	Heart Failure
2	Cerebrovasecular Disease
3	External Forces Causing Death
4	Ischemic heart disease
5	Renal Failure
6	Septeciemia
7	Respiratory Distress Syndrom
8	Senility
9	Diabetus Mellutis
10	Malignant Tumour of G.I.T

The top 10 diseases causing morbidity in Iraq are

	Disease
1	Gastroenteritis
2	Bronchitis
3	Pneumonia
4	Cardiovascular Disease
5	Urinary System Disorders
6	Abortion
7	Measles
8	Hernia
9	Respiratory Distress Syndrom
10	Diabetes Mellitus

Source: MOH/Directorate of Planning & Human resource development, 2009

Section 2 - Health Services

This section provides information regarding health expenditures and human resources for health in Iraq. The contribution of the public and private sector to overall health expenditure is shown and the specific information on pharmaceutical expenditure is also presented. Data on human resources for health and for the pharmaceutical sector is provided as well.

2.1 Health Expenditures

In Iraq, the total annual expenditure on health (THE) in 2008 was 5,138,643 million Iraqi dinars (IQD) (US$ 4,392 million)[6]. The total annual health expenditure was 3.9 % of the GDP. The total annual expenditure on health per capita was 158,963 IQD (US$ 136)[7].

The general government[ii] health expenditure (GGHE) in 2008, as reflected in the national health accounts (NHA) was 3,760,586 million IQD (US$ 3,214 million). That is, 73.18 % of the total expenditure on health, with a total annual per capita public expenditure on health of 116,333 IQD (US$ 99.43). The government annual expenditure on health represents 3.06 % of the total government budget. Private health expenditure covers the remaining 26.82 % of the total health expenditure.

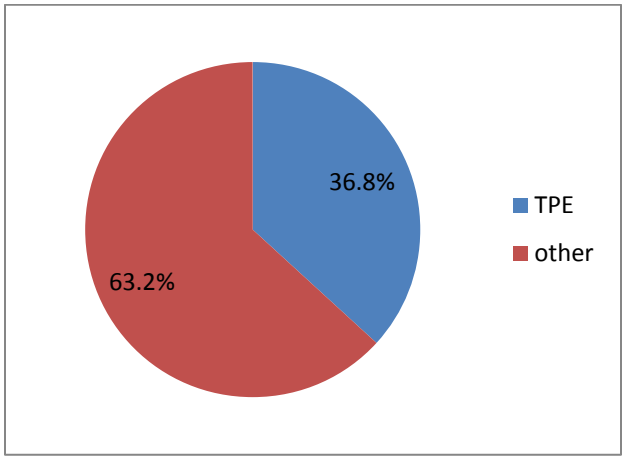
Of the total population, 100 % is covered by a public health service, public health insurance or social insurance, or other sickness funds. The percentage of population covered by a private health insurance is unknown.

Total pharmaceutical expenditure (TPE) in Iraq in 2008 was 1,892,415 million IQD (US$ 1,617 million), which is a per capita pharmaceutical expenditure of

[ii] According to the NHA definition, by "government expenditure" it is meant all expenditure from public sources, like central government, local government, public insurance funds and parastatal companies.

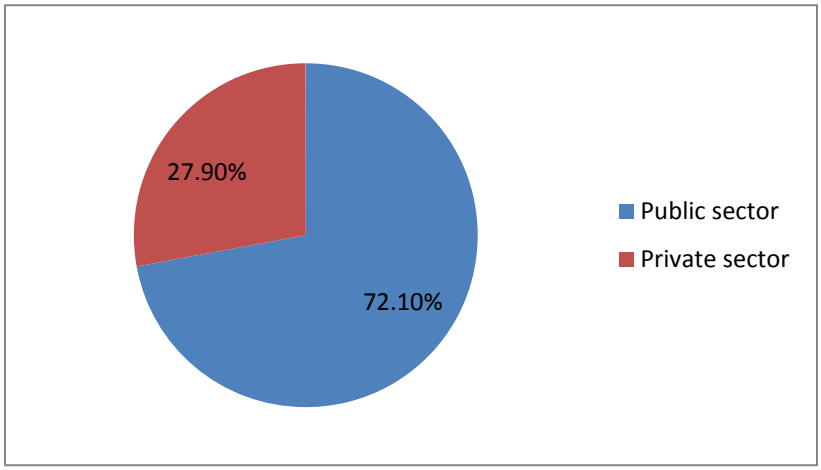
58,542 IQD (US$ 50). The total pharmaceutical expenditure accounts for 2.46 % of the GDP and makes up 36.8 % of the total health expenditure (Figure 1). Public expenditure on pharmaceuticals represents 72.1 % of the total expenditure on pharmaceuticals (Figure 2), this converts into a per capita public expenditure on pharmaceuticals of 42,235 IQD (US$ 36)[8].

FIGURE 1: Share of Total Pharmaceutical Expenditure as percentage of the Total Health Expenditure 2008. The THE in 2008 was 5,138,643 million IQD (US$ 4,392 million)



NHA, 2008

FIGURE 2: Share of Total Pharmaceutical Expenditure by sector 2008



NHA, 2008

Total private expenditure on pharmaceuticals is 527,117 million IQD (US$ 450 million).

Social security expenditure makes up 0 % of government expenditure on health. There are is no private health insurance in Iraq.

2.2 Health Personnel and Infrastructure

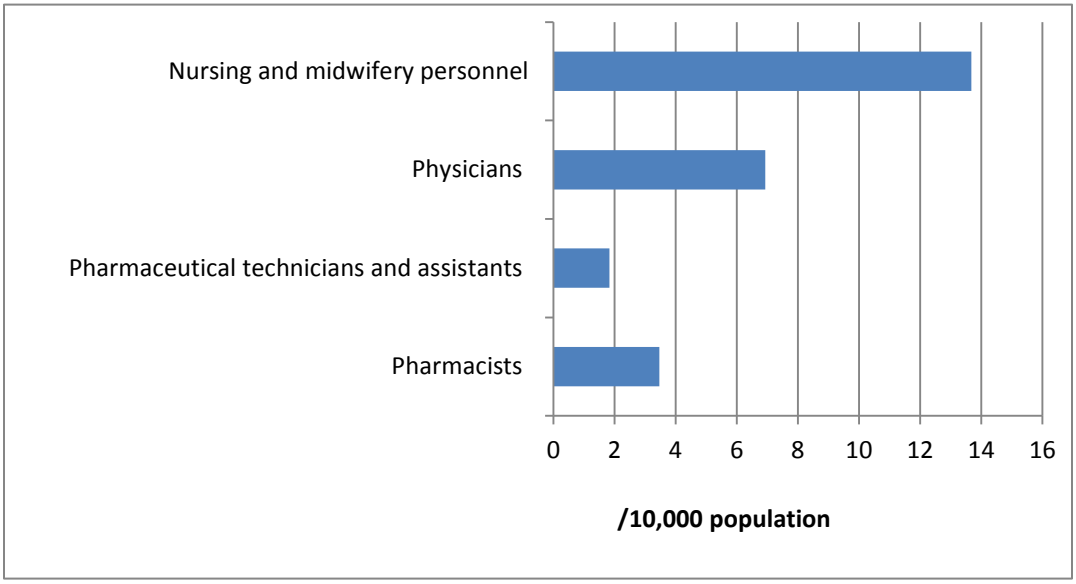
The health workforce is described in the table below and in Figure 3. There are 11,206 (3.47/10,000) licensed pharmacists, of which 5,376 (1.66 /10,000) work in the public sector. There are 5,910 (1.83 /10,000) pharmaceutical technicians and assistants (in all sectors).

There are 22,396 (6.93 /10,000) physicians and 44,201 (13.67 /10,000) nursing and midwifery personnel in Iraq. The ratio of doctors to pharmacists is 1.99 and the ratio of doctors to nurses and midwifery personnel is 0.51.[5]

Table 1: Human resources for health in Iraq (2009)[5]

Human Resource	
Licensed pharmacists (all sectors)	11,206 (3.47/10,000)
Pharmacists in the public sector	5,376 (1.66 /10,000)
Pharmaceutical technicians and assistants (all sectors)	5,910 (1.83 /10,000)
Physicians (all sectors)	22,396 (6.93 /10,000)
Nursing and midwifery personnel (all sectors)	44,201 (13.67 /10,000)

Figure 3: The density of the Health Workforce 2009 in Iraq (all sectors)



MOH, 2009

In Iraq, there is a strategic plan for pharmaceutical human resource development in place. This plan is developed annually. The key areas include pharmaceutical services in words, drug & therapeutic committee, pharmacovigilance, drug industry, drug regulatory authority and rational drug use.[9]

The health workforce is described in the table below and in Table 2. There are 220 hospitals and 13 hospital beds / 10,000 population in Iraq. There are 2,168 primary health care units and centres and 9,500 licensed pharmacies.

Table 2: Health centre and hospital statistics

Infrastructure	
Hospitals	220[5]
Hospital beds	13/10,000[1]
Primary health care units and centres	2,168[5]
Licensed pharmacies	9,500[10]

The annual starting salary for a newly registered pharmacist in the public sector is 362,000 IQD. The total number of pharmacists who graduated (as a first

degree) in the past 2 years is 1,089.[11] Accreditation requirements for pharmacy schools are in place. The pharmacy Curriculum is regularly reviewed.

Further key findings:

- Which is the highest area of priority for HR development?
  - pharmaceutical services in words
  - drug & therapeutic committee
  - Pharmacovigilance
  - drug regulatory authority
  - rational drug use

- Are new medical or pharmacy schools opening?
  - Yes

- What about pharmaceutical technician training?
  - Yes, there is a practical training for the pre- & post-graduated pharmaceutical technicians

- Are there going to be more hospitals or primary care units constructed in future?
  - Yes

- Are licensed pharmacies widely located or concentrated in the capital?
  - Licensed pharmacies are widely located.

- Are there any specific plans or policies to improve retention of nationally trained healthcare workers? (is this an area of concern?)
  - Yes

- Which partners are working with you or supporting initiatives in the areas discussed in this section? What projects are they involved in and how are they assisting or collaborating?
  - Partners include: WHO, The World Bank, donor countries
  - Those pretenders involved in conducting a training courses outside the country, bringing a professionals & advisors for assistant in development of health system, re-habitation & building

Section 3 - Policy Issues

This section addresses the main characteristics of the pharmaceutical policy in Iraq. The many components of a national pharmaceutical policy are taken from the WHO publication "How to develop and implement national drug policy" (http://apps.who.int/medicinedocs/en/d/Js2283e/). Information about the capacity for manufacturing medicines and the legal provisions governing patents is also provided.

3.1 Policy Framework

In Iraq, a National Health Policy (NHP) does not exist. Policy is implemented through ministerial instructions and orders.

An official National Medicines Policy document exists in Iraq[12]. It was updated in 2008. A NMP implementation plan does not exist. Policies addressing pharmaceuticals exist, as detailed in Table 2. Pharmaceutical policy implementation is not regularly monitored/assessed.

Table 3: The NMP covers[12]

Aspect of policy	Covered
Selection of essential medicines	Yes
Medicines financing	Yes
Medicines pricing	Yes
Medicines Procurement	Yes
Medicines Distribution	Yes
Medicines Regulation	Yes
Pharmacovigilance	Yes
Rational use of medicines	Yes
Human Resource Development	Yes
Research	Yes
Monitoring and evaluation	Yes

Traditional Medicine	Yes

A policy relating to clinical laboratories exists and is updated annually (most recent update in 2011)[13]. An associated National clinical laboratory policy implementation plan, developed in 2011, also exists[14]. Access to essential medicines/technologies as part of the fulfillment of the right to health, is recognized in the constitution or national legislation[15]. There are official written guidelines on medicines donations[16].

There is no national good governance policy in Iraq. However, MOH Iraq has joined the WHO GGM programme in December 2010.

A policy is in place to manage and sanction conflict of interest issues in pharmaceutical affairs (Comment: only managerial and ministerial instructions exist.). There is no associated formal code of conduct for public officials. A whistle-blowing mechanism that allows individuals to raise concerns about wrongdoing occurring in the pharmaceutical sector of Iraq exists[17].

Section 4 - Medicines Trade and Production

4.1 Intellectual Property Laws and Medicines

Iraq is not a member of the World Trade Organization. Legal provisions granting patents to manufacturers exist. These cover pharmaceuticals, laboratory supplies, medical supplies and medical equipment.

Intellectual Property Rights are managed and enforced by the Ministry of Planning/Central Organization for Standardization and Quality Control (COSQC).

National Legislation has not been modified to implement the TRIPS Agreement and does not contain TRIPS-specific flexibilities and safeguards, presented in Table 4. Iraq is not eligible for the transitional period to 2016.

Table 4: TRIPS flexibilities and safeguards are present in the national law

Flexibility and safeguards	Included
Compulsory licensing provisions that can be applied for reasons of public health	No
Bolar exceptions[iii]	No
Parallel importing provisions	No

[iii] Many countries use this provision of the TRIPS Agreement to advance science and technology. They allow researchers to use a patented invention for research, in order to understand the invention more fully.
In addition, some countries allow manufacturers of generic drugs to use the patented invention to obtain marketing approval (for example from public health authorities) without the patent owner's permission and before the patent protection expires. The generic producers can then market their versions as soon as the patent expires. This provision is sometimes called the "regulatory exception" or "Bolar" provision. *Article 30*
This has been upheld as conforming with the TRIPS Agreement in a WTO dispute ruling. In its report adopted on 7 April 2000, a WTO dispute settlement panel said Canadian law conforms with the TRIPS Agreement in allowing manufacturers to do this. (The case was titled "Canada - Patent Protection for Pharmaceutical Products")
[In: WTO OMC Fact sheet: TRIPS and pharmaceutical patents, can be found online at: http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf]

There are legal provisions for patent term extension and linkage between patent status and marketing authorization, but no legal provisions for data exclusivity for pharmaceuticals.[18]

The country is not engaged in capacity-strengthening initiatives to manage and apply Intellectual Property Rights in order to contribute to innovation and promote public health.

4.2 Manufacturing

There are 23 licensed pharmaceutical manufacturers in Iraq. Manufacturing capabilities are presented in Table 5 below.

Table 5: Iraq manufacturing capabilities[19]

Manufacturing capabilities	
Research and Development for discovering new active substances	No
Production of pharmaceutical starting materials (APIs)	No
The production of formulations from pharmaceutical starting material	Yes
The repackaging of finished dosage forms	No

Section 5 – Medicines Regulation

This section details the pharmaceutical regulatory framework, resources, governing institutions and practices in Iraq.

5.1 Regulatory Framework

In Iraq, there are no legal provisions establishing the powers and responsibilities of the Medicines Regulatory Authority (MRA).

Comment: There is no law or act that provides power and responsibilities to a MRA in Iraq. There are ministerial orders, laws here and there, but not one clear document that regulates the work of a MRA. The Directorate of Technical Affairs in the Ministry of Health in addition to the state owned public pharmaceutical procurement and distribution company (KIMADIA)[40] and the Syndicate of Pharmacy[10] play the role of a MRA.

The MRA is a part of the MOH with a number of functions outlined in Table 6.
The MRA has its own website, for which the URL is www.techmoh.net.

Table 6: Functions of the national MRA

Function	
Marketing authorisation / registration	Yes
Inspection	Yes
Import control	Yes
Licensing	Yes
Market control	Yes
Quality control	Yes
Medicines advertising and promotion	Yes
Clinical trials control	Yes
Pharmacovigilance	Yes

The MRA receives external technical assistance to support its activities: The WHO Iraq Country Office provides external technical assistance at different regulatory functions (quality control, registration, GMP). The MRA is not involved in harmonization/collaboration initiatives. An assessment of the medicines regulatory system has not been conducted in the last five year. Funding for the MRA is provided through the regular government budget, as well as through additional sources, including WHO. The Regulatory Authority does not retain revenues derived from regulatory activities. This body utilizes a computerized information management system to store and retrieve information on processes that include registrations, inspection etc.[20]

5.2 Marketing Authorization (Registration)

In Iraq, legal provisions requires marketing authorization (registration) for all pharmaceutical products on the market, however exceptions/waivers for registration do exist.[21] Mutual recognitions mechanisms are not in place. Explicit and publicly available criteria exist for assessing applications for marketing authorization of pharmaceutical products.[22] In 2011, there were 7,000 pharmaceutical products registered in Iraq. There are legal provisions requiring the MRA to make the list of registered pharmaceutical products publicly available and update it regularly. This register is updated every month. The updated list can be accessed through www.techmoh.net. Medicines are not always registered by their INN (International Non-proprietary Names) or Brand name + INN. Legal provisions require a fee to be paid for Medicines Market Authorization (registration) based on applications[23].

Marketing Authorization holders are required by law to provide information about variations to the existing Marketing Authorization. Legally, a Summary of Product Characteristics (SPC) of the medicines that are registered is required to be published. However, legal provisions requiring the establishment of an expert committee involved in the Marketing Authorization process are not in place.

Possession of a Certificate for Pharmaceutical Products (that accords with the WHO Certification scheme) is required as part of the Marketing Authorization application. By law, potential conflict of interests for experts involved in the assessment and decision-making for registration must be declared. Applicants may legally appeal MRA decisions.

The registration fee (per application) for a pharmaceutical product containing a New Chemical Entity (NCE) and for a generic pharmaceutical is US$ 165.

5.3 Regulatory Inspection

In Iraq, legal provisions exist allowing for appointment of government pharmaceutical inspectors[24]. Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed; such inspections are required by law and are a pre-requisite for the licensing of public and private facilities[25]. Where inspections are legal requirements, these are not the same for public and private facilities. Inspections are carried out on a number of entities, outlined in Table 7.

Table 7: Local entities inspected for GMP compliance[25]

Entity	Inspection
Local manufacturers	Yes
Private wholesalers	Yes
Retail distributors	Yes
Public pharmacies and stores	Yes
Pharmacies and dispensing points if health facilities	Yes

5.4 Import Control

Legal provisions exist requiring authorization to import medicines. Laws exist that allow the sampling of imported products for testing.

Legal provisions exist requiring importation of medicines through authorized ports of entry. Regulations or laws exist to allow for inspection of imported pharmaceutical products at authorized ports of entry[26].

5.5 Licensing

In Iraq, legal provisions exist requiring manufacturers to be licensed (MOH, 2007)[27]. Legal provisions exist requiring manufacturers (both domestic and international) to comply with Good Manufacturing Practices (GMP). Good Manufacturing Practices are not published by the government.

Legal provisions exist requiring importers/wholesalers/distributers to be licensed[28]. Legal provisions do not exist requiring wholesalers and distributors to comply with Good Distributing Practices.

Table 8: Legal provisions pertaining to licensing

Entity requiring licensing	
Importers	Yes
Wholesalers	Yes
Distributors	Yes

Good Distribution Practices are not published by the government.

Legal provisions exist requiring pharmacists to be registered. Legal provisions exist requiring private and public pharmacies to be licensed[24]. National Good Pharmacy Practice Guidelines are published by the government[29]. By law, a list of all licensed pharmaceutical facilities is required to be published.

5.6 Market Control and Quality Control

In Iraq, legal provisions exist for controlling the pharmaceutical market.[24,30] A laboratory exists in Iraq for Quality Control testing.

The laboratory is not a functional part of the MRA.

Existing national laboratory facilities have not been accepted for collaboration with the WHO pre-qualification Programme. Medicines are tested for a number of reasons, summarised in Table 9.

Table 9: Reason for medicines testing[31]

Medicines tested:	
For quality monitoring in the public sector[iv]	No
For quality monitoring in the private sector[v]	Yes
When there are complaints or problem reports	Yes
For product registration	Yes
For public procurement prequalification	No
For public program products prior to acceptance and/or distribution	Yes

Samples are collected by government inspectors for undertaking post-marketing surveillance testing. In the past 2 years, 12,000 samples were taken for quality control testing. Of the samples tested, 0 failed to meet the quality standards. The results are publicly available[32].

5.7 Medicines Advertising and Promotion

In Iraq, legal provisions exist to control the promotion and/or advertising of prescription medicines. The MOH is responsible for regulating promotion and/or advertising of medicines. Legal provisions prohibit direct advertising of prescription medicines to the public and pre-approval for medicines advertisements and promotional materials is not required. Guidelines and

[iv] Routine sampling in pharmacy stores and health facilities
[v] Routine sampling in retail outlets

Regulations do not exist for advertising and promotion of non-prescription medicines. There is no national code of conduct concerning advertising and promotion of medicines by marketing authorization holders.

5.8 Clinical Trials

In Iraq, legal provisions exist requiring authorization for conducting Clinical Trials by the MRA. There are no additional laws requiring the agreement by an ethics committee or institutional review board of the Clinical Trials to be performed. Clinical trials are required to be entered into an international/national/regional registry, by law[33].

Legal provisions exist for GMP compliance of investigational products. Sponsor investigators are legally required to comply with Good Clinical Practices (GCP). National GCP regulations are not published by the Government. Legal provisions permit the inspection of facilities where clinical trials are performed.[33]

5.9 Controlled Medicines

Iraq is a signatory to a number of international conventions, detailed in Table 10.

Table 10: International Conventions to which Iraq is a signatory[34]

Convention	Signatory
Single Convention on Narcotic Drugs, 1961	Yes
1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	Yes
Convention on Psychotropic Substances 1971	Yes
United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	Yes

Laws exist for the control of narcotic and psychotropic substances, and precursors.[35] The annual consumption of Morphine is 0.250000 mg/capita[36].

Figures regarding the annual consumption of certain controlled substances in the country are outlined in Table 10S below.

Table 10S: Annual consumption of selected controlled substances in Iraq

Controlled substance	Annual consumption (mg/capita)
Morphine	0.250000
Fentanyl	0.003125
Pethidine	2.03125
Oxycodone	.00125
Phenobarbital	8

5.10 Pharmacovigilance

In Iraq, there are no legal provisions in the Medicines Act that provide for pharmacovigilance activities as part of the MRA mandate**.** Legal provisions do not exist requiring the Marketing Authorization holder to continuously monitor the safety of their products and report to the MRA. Laws regarding the monitoring of Adverse Drug Reactions (ADR) do not exist in Iraq. A national pharmacovigilance centre linked to the MRA exists. The Pharmacovigilance centre has 4 full-time staff members.

The centre has not published an analysis report in the previous two years and it regularly does not publish an ADR bulletin. An official standardized form for reporting ADRs is used in Iraq. Information pertaining to ADRs is stored in a national ADR database. The ADR database currently comprises 40 ADR reports, of which 40 have been submitted in the past 2 years. These reports are also sent to the WHO collaborating centre in Uppsala[37]. 23 ADR reports from the database have been forwarded to the WHO collaborating centre in the past 2 years.

There is a national ADR or pharmacovigilance advisory committee able to provide technical assistance or causality assessment, risk assessment, risk

management, case investigation and, where necessary, crisis management including crisis communication in Iraq. A clear communication strategy for routine communication and crises communication does not exist.

ADRs are monitored in at least one public health program (example TB, HIV, AIDS).

A number of steps are being considered in order to enhance Pharmacovigilance system. These include:

1- Regenerating a pharmacovigilance law
2- Regenerating guidelines specially for Iraq
3- Regenerating a training package for Iraq

Section 6 - Medicines Financing

In this section, information is provided on the medicines financing mechanism in Iraq, including the medicines coverage through public and private health insurance, use of user charges for medicines and the existence of public programmes providing free medicines. Policies and regulations affecting the pricing and availability of medicines (e.g. price control and taxes) are also discussed.

6.1 Medicines Coverage and Exemptions

In Iraq, concessions are made for certain groups to receive medicines free of charge (see Table 12). Furthermore, the public health system or social health insurance schemes provide medicines free of charge for particular conditions (see Table 13).

Table 12: Population groups provided with medicines free of charge[38]

Patient group	Covered
Patients who cannot afford them	Yes
Children under 5	Yes
Pregnant women	Yes
Elderly persons	Yes

Table 13: Medications provided publicly, at no cost[39]

Conditions	Covered
All diseases in the EML	Yes
Any non-communicable diseases	Yes
Malaria	Yes
Tuberculosis	Yes
Sexually transmitted diseases	Yes
HIV/AIDS	Yes
Expanded Program on Immunization (EPI) vaccines for children	Yes
any other health problem	Yes

A public health service, public health insurance, social insurance or other sickness fund does not provide at least partial medicines coverage.

Private health insurance schemes do not provide medicines coverage. In Iraq, there is no private health insurance. All Iraqis receive health care and medicines either free of charge or for a very minimal (symbolic) fee.

6.2 Patients Fees and Co-payments

Co-payments or fee requirements for consultations are levied at the point of delivery. There are no copayments or fee requirements imposed for medicines. Revenue from fees or from the sale of medicines is not used to pay the salaries or supplement the income of public health personnel in the same facility.

6.3 Pricing Regulation for the Private Sector[vi]

In Iraq, there are no legal or regulatory provisions affecting pricing of medicines. The government does not run an active national medicines price monitoring system for retail prices. Regulations do not exist mandating that retail medicine price information should be publicly accessible.

[vi] This section does not include information pertaining to the non-profit voluntary sector

6.4 Prices, Availability and Affordability of Key Medicines

A WHO/HAI pricing survey has not been conducted in the past 5 years.

6.5 Price Components and Affordability

A survey on medicine price components has not been conducted in the past 5 years.

6.6 Duties and Taxes on Pharmaceuticals (Market)

Iraq does not impose duties on imported active pharmaceutical ingredients (APIs) and duties on imported finished products are also not imposed. Value-added tax or other taxes are not imposed on finished pharmaceutical products. Provisions for tax exceptions or waivers for pharmaceuticals and health products are in place[40]. Medicines are not subjected to taxes.

Section 7 - Pharmaceutical procurement and distribution in the public sector

This section provides a short overview on the procurement and distribution of pharmaceuticals in the public sector of Iraq.

7.1 Public Sector Procurement

Public sector procurement in Iraq is both centralized and decentralized/decentralized[40].

The public sector procurement is centralized under the responsibility of a procurement agency which is a part of the MOH and semi-autonomous.[40]

Public sector request for tender documents are publicly available and public sector tender awards are publicly available. Procurement is not only based on the prequalification of suppliers, in addition the manufacturer & the medicines should be preregistered.[40]

There is a written public sector procurement policy.
Legal provisions exist that give priority to locally produced goods in public procurement. (Iraqi constitution, 2005)
The key functions of the procurement unit and those of the tender committee are clearly separated. A process exists to ensure the quality of products that are publicly procured (Law of Public Health No 89, 1981).
The quality assurance process includes the pre-qualification of products and suppliers. A list of pre-qualified suppliers and products is available.
A list of samples tested during the procurement process and the results of quality testing are available. The tender methods employed in public sector procurement include, national competitive tenders, international competitive tenders and direct purchasing.

7.2 Public Sector Distribution

The government supply system department in Iraq has 6 Central Medical Stores at national level and 5 regional Medical Stores (the central stores are also known as Al-Dabbash, Al-Eskan, Al-Haswa, Al-Ameria, Al-Adel, and Engineering store – spear part)[40]. There are 6 public warehouses in the secondary tier of the public sector distribution. There are no national guidelines on Good Distribution Practices (GDP). A licensing authority that issues GDP licenses does not exist[40]. A list of GDP certified wholesalers or distributors does not exist in the public sector.

7.3 Private Sector Distribution

Legal provisions exist for licensing wholesalers in the private sector.[24] A list of GDP certified wholesalers or distributors does not exist in the private sector.

Section 8 - Selection and rational use of medicines

This section outlines the structures and policies governing the selection of essential medicines and promotion of rational drug in Iraq.

8.1 National Structures

A National Essential Medicines List (EML) exists.

The EML was lastly updated in 2011 and is publicly available.[41]

There are currently 1,259 medicines on the EML. Selection of medicines for the EML is undertaken through a written process. A mechanism aligning the EML with the Standard Treatment Guidelines (STGs) is not in place[42].

National Standard Treatment Guidelines (STGs) for the most common illnesses are not produced/endorsed by the MOH in Iraq.

Of the public health facilities, 100 % have a copy of the EML.

There is no public or independently funded national medicines information centre providing information on medicines to prescribers, dispensers and consumers. Public education campaigns on rational medicine use topics have not been conducted in the last two years. A survey on rational use of medicines has not been conducted in the previous two years. There is a national programme or committee, involving government, civil society, and professional bodies, to monitor and promote rational use of medicines.

A written National Strategy for containing antimicrobial resistance exists and was last updated in 2010[43].

Iraq's Essential Medicines List (EML) includes formulations specifically for children. Criteria for the selection of medicines to the EML are explicitly documented. A national medicines formulary does exist.

A funded national intersectoral task force to coordinate the promotion of the appropriate use of antimicrobials and prevention of the spread of infection does not exist.

A national reference laboratory or other institution has responsibility for coordinating epidemiological surveillance of antimicrobial resistance.

8.2 Prescribing

Legal provisions exist to govern the licensing and prescribing practices of prescribers. Furthermore, legal provisions restricting dispensing by prescribers exist. Prescribers in the private sector do not dispense medicines[44].

There are regulations requiring hospitals to organize/develop Drug and Therapeutics Committees (DTCs)[44]. Where there are requirements for DTCs, more than half of referral/ general/regions/provinces have one.

The training curriculum for doctors and nurses is made up of a number of core components detailed in Table 16.

Table 16: Core aspects of the medical training curriculum[45]

Curriculum	Covered
The concept of EML	Yes
Use of STGS	No
Pharmacovigilance	Yes
Problem based pharmacotherapy	Yes

Mandatory continuing education that includes pharmaceutical issues is required for doctors, nurses and paramedical staff.

Prescribing by INN name is obligatory in the public sector, but not in the private sector[46]. The average number of medicines prescribed per patient contact in public health facilities is 3. Of the medicines prescribed in the outpatient public health care facilities 100 % are prescribed by INN name. Of the patients treated in the outpatient public health care facilities, 71.7 % receives antibiotics. Of prescribed drugs, 95 % are dispended to patients. Of medicines in public health facilities, 100 % are adequately labelled.

Table 17: Characteristics of medicines prescribing

Curriculum	%
% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)	unknown
% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)	100
% of patients in outpatient public health care facilities receiving antibiotics (mean)	71.7
% of patients in outpatient public health care facilities receiving injections (mean)	unknown
% of prescribed drugs dispensed to patients (mean)	95
% of medicines adequately labeled in public health facilities (mean)	100

A professional association code of conduct which governs the professional behaviour of doctors or nurses does not exist

8.3 Dispensing

Legal provisions in Iraq do not exist to govern dispensing practices of pharmaceutical personnel[47]. The basic pharmacist training curriculum includes a spectrum of components as outlined in Table 18.

Table 18: Core aspects of the pharmacist training curriculum

Curriculum	Covered
The concept of EML	Yes
Use of STGS	Yes
Drug information	Yes
Clinical pharmacology	Yes
Medicines supply management	Yes

Mandatory continuing education that includes rational use of medicines is required for pharmacists.

Substitution of generic equivalents at the point of dispensing is allowed in public sector facilities[48]. Sometimes antibiotics are sold over-the-counter without a prescription. Sometimes injectable medicines are sold over-the-counter without a prescription.

Section 9 - Household data/access

This section provides information derived from past household surveys in Iraq regarding actual access to medicines by normal and poor households.

Comment: The Iraq Family Health Survey was conducted in 2005. Data for this section is not available.

List of key reference documents:

[1] World Health Organization (WHO) (2010), "World Health Statistics 2010", WHO Press, Geneva. Available at: http://www.who.int/whosis/whostat/2010/en/index.html.

[2] World Health Organization (WHO) (2009), "World Health Statistics 2009", WHO Press, Geneva. Available at: http://www.who.int/whosis/whostat/2009/en/index.html.

[3] Central Organization for Statistics and Information Technology (COSIT) (2009). Online: http://cosit.gov.iq/english/ .

[4] Annual report 2009, Directorate of Planning & Human resource development, MOH Iraq. The population growth rate does not include Kurdistan regional Government (KRG).

[5] Data provided by MOH Iraq (2009).

[6] Iraq National Health Account (NHA) (2008), April 2011

[7] Calculated based on data provided in draft of Iraq NHA 2008 and COSIT 2009.

[8] Calculated based on data provided in draft of Iraq National Health Account (NHA) 2008, April 2011

[9] Strategic plan from 2010, Data provide by MOH Iraq

[10] Syndicate of Iraqi Pharmacists (2010). Online: http://www.iraqipharm.com/

[11] MOH (2010)

[12] Iraqi National Medicines Policy, 2009, Ministry of Health - Republic of IRAQ, Available at: http://www.emro.who.int/emp/IRQ_NMP_09.PDF (Arabic)

[13] MOH (2011)

[14] MOH (2011)

[15] Iraqi constitution (2005). Available at: http://www.uniraq.org/documents/iraqi_constitution.pdf

[16] Guidelines from year 2008, Information provided by MOH in 2011.

[17] MOH (2011)

[18] Ministry of Planning / Central office for Standardization & Quality control / Law of patent & industerial samples no.56 at 2000

[19] MOH (2011)

[20] MOH (2011)

[21] MOH (2011)

[22] MOH (2011)

[23] MOH (2011)

[24] Law of practicing pharmacy (1970)

[25] MOH (2007)

[26] Official Regulation no 60, MOH (1998)

Law of Public Health (1981), Official Regulation no. 2 year 2001, MOH

Ministerial Instructions (2008)

[27] MOH (2007)

[28] MOH (2007)

[29] Ministerial Instructions and Booklet for Good Pharmacy Practice (2010)

[30] Continuous ministerial Instruction (2011)

[31] MOH (2010)

[32] MOH (2011)

[33] Law of public health and official regulation no 8, MOH (2001)

[34] United Nations Treaty collection, Status of Treaties. Available online: http://treaties.un.org/pages/ParticipationStatus.aspx.

[35] Law No. 68 of 1965 on Narcotic Drugs

[36] INCB (2011)

[37] MOH (2011)

[38] WHO level I survey

[39] Constitution of Iraq

[40] The State Company For Marketing Drugs And Medical Appliances (KIMADIA) (2011), online: http://www.kimadia-iraq.com.

[41] National Essential Medicine List, available at http://www.who.int/selection_medicines/country_lists/en/index.html.

[42] MOH (2011)

[43] MOH (2010)

[44] MOH (2007)

[45] MOH

[46] MOH

[47] MOH (2010)

[48] MOH (2011)

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Pharmaceutical Sector Country Profile Questionnaire

IRAQ

The Pharmaceutical Sector Country Profile Survey

1. Background and Rationale:

Pharmaceutical Sector Country Profiles aim to increase the availability of quality information on structures, processes and outcomes of health and pharmaceutical sectors of countries. This information will be collected through a questionnaire and is meant to be used by country decision-makers, health and pharmaceutical experts, international partners and the public through databases and published country, regional and global reports.

The information is categorized in nine sections, namely: (1) Health and Demographic data, (2) Health Services, (3) Medicines Policies, (4) Medicines Trade and Production, (5) Medicines Regulation, (6) Medicines Financing, (7) Pharmaceutical Procurement and distribution, (8) Selection and Rational Use and (9) Household data/access.

Every four years since 1999, health officials from the 193 WHO Member States have been invited to complete a standardized questionnaire (named Level I) reporting on the status of the national pharmaceutical situation. Level I indicators assessed structures and processes related to the pharmaceutical situation of a country. They were used to carry out a rapid assessment that would highlight strengths and weaknesses of countries pharmaceutical situations. 156 countries responded to the 2007 level I survey and the results were stored and available in a global WHO database and used to develop a global report as well as a number of regional and sub-regional reports. The Pharmaceutical Sector Country Profile questionnaire described here will replace the Level I tool for the 2011 Member States' survey. The aim of this new approach is to build on the achievements and lessons learnt from the Level I tools and surveys and to improve the quality and scope of information (e.g, outcomes and results indicators) and enhance the involvement and ownership of countries in the development of profiles. The new tool has been piloted in the 15 countries of the Southern African Development Community in 2009 and in 13 countries across the world in 2010. The results of these pilots are available on-line at: http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index.html

Another innovation of the 2011 survey is the collaboration between WHO and The Global Fund. In 2009, the Global Fund developed and introduced the Pharmaceutical and Health Product Management ("PHPM") Country Profile to gradually replace the Procurement and Supply Management ("PSM") Plan. In the course of 2010 both agencies have developed a joint Pharmaceutical Sector Country Profile questionnaire that includes key indicators of the

pharmaceutical sector and that will be used by both agencies as the sole tool for pharmaceutical sector data collection in countries. The information captured in the Pharmaceutical Sector Country Profile questionnaire will be used by the Global Fund during grant negotiations and signing, and will also support grant implementation. In addition to the Country Profile that provides an overview of countries' pharmaceutical sectors, the Global Fund will also use a second questionnaire that will focus in more detail on medicines procurement and supply.

2. What can Pharmaceutical Sector Country Profiles offer:

Completing this questionnaire will require the time of national experts and responsible officers but it is worthwhile as your country and your partners will benefit from it in a number of ways:

I) The questionnaire offers a unique opportunity to consolidate, in one place, information that is available in different locations and institutions e.g. the National Medicines Regulatory Authority, Central Medical Stores, National Health Accounts, etc.

II) The methodology proposed for filling in the questionnaire will ensure that good quality data are collected and that the source and date of information are known and reported.

III) Data on structure, process and outcomes are collected, and the questionnaire has been pre-filled with data available in the public domain; indicators are divided into core and supplementary in order to make it easier to identify what is more important.

IV) The data collected will highlight the strengths and weaknesses of the pharmaceutical sector and will be made available in a national database as official country information, for use by decision-makers, health and pharmaceutical experts, researchers and international partners and the public..

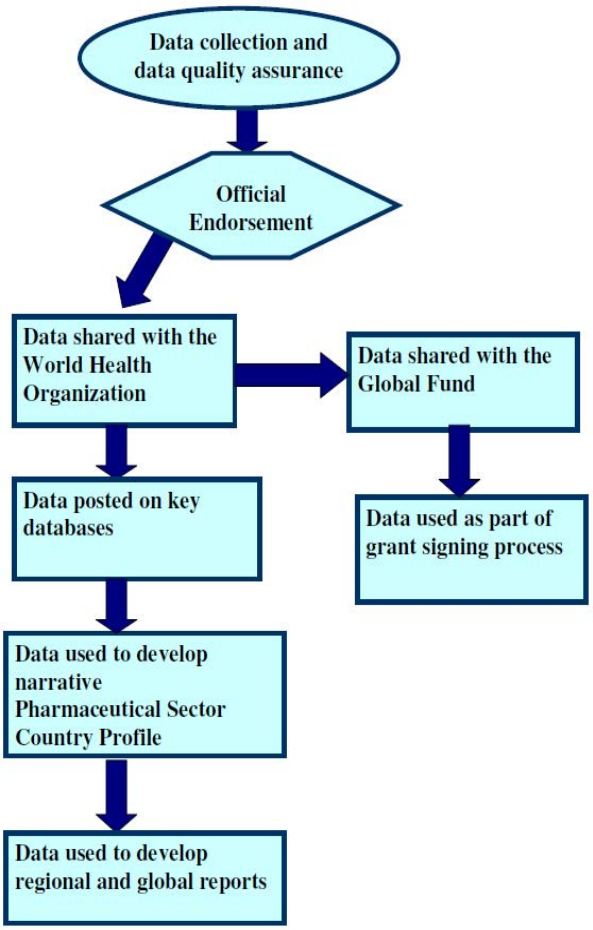
V) The data collected could be transformed into a narrative report with robust data analysis and bibliographic references, that will summarize the medicines situation in the country.

VI) Based on experiences from previous surveys, a detailed glossary of key definitions and a manual for use of the questionnaire have been developed and can be found at the end of the questionnaire.

3. The process of data collection and analysis:

3.1 Data collection. The Pharmaceutical Sector Country Profile questionnaire has already been filled in by WHO with reliable data available from global and country sources. We kindly ask you to review, to correct (if necessary) and to validate the information already included in the questionnaire, and also to fill in the gaps, based on reliable information available in your country.

In order to do this, we recommend that you involve the most appropriate respondents and responsible institutions to fill in the various components of the tool so that the questionnaire is completed within the given deadline, with good quality information. If during the data collection process, clarifications are needed, WHO Regional and Headquarters Offices will provide the necessary assistance and support, including for data quality issues.



3.2 Official endorsement. Once the questionnaire has been completed, the information contained in it should be officially endorsed and its disclosure authorized by a senior official in the Ministry of Health. This should be done by signing the formal endorsement form attached to the questionnaire. This will ensure that the quality of the information contained in the Pharmaceutical Sector Country Profile questionnaire is certified by the country.

3.3 Data shared with the Global Fund. Data collected from Global Fund priority countries will be shared with the Global Fund and it will be used as part of the Global Fund's own grant signing and implementation procedures.

3.4 Data posted on key databases. Data endorsed by the country will be posted on health databases (such as the WHO Global Health Observatory, http://www.who.int/gho/en/), making it available to decision-makers, health and medicines experts and researchers, international partners and the public.

3.5 Development of narrative Pharmaceutical Sector Country Profiles. Data provided within the country questionnaire can be used by the country to develop a narrative profile that will illustrate the national pharmaceutical sector. In order to do this, WHO has prepared a template profile (included in the CD-Rom shared with you) that can be easily used by countries and that will help presenting data in the form of tables, graphs and charts. Countries could seek support from WHO for the development of their narrative profile, which will be finalized and validated by the country that will own the copyright for it and will publish it as a national official document.

3.6 Development of Regional and Global Reports. The information provided by countries in the Pharmaceutical Sector Country Profile questionnaire will be analysed by WHO and used to produce regional and global reports on the pharmaceutical sector of countries in 2011. These reports will provide an overview of the progress made between 2007 and 2011, of the challenges that remain to be addressed and will include data analysis by technical areas, countries' income level and geographical location.

Guidelines for countries on how to fill in the Pharmaceutical Sector Country Profile Questionnaire

Please read these instructions carefully before starting data collection

1. Macros: the questionnaire has macros installed. A macro is a series of MS Word commands and instructions that are grouped together as a single command to accomplish a task automatically. For these macros to work properly, the macro security levels for MS Word on your computer should be set as 'low'. This can be easily adjusted by taking the following steps:

1. Open the Word document containing the instrument.
2. Go to 'Tools' > 'Macro' > 'Security'.
3. Click on the tab 'Security Level'.
4. Set the Security on 'Low' and click 'OK'.

After filling in the questionnaire, the setting should be restored to a higher level of security in order to protect your computer.

2. Core and supplementary indicators: the instrument consists of core and supplementary questions. Core questions cover the most important information, while supplementary questions deal with more specific information applicable to particular sections. Please note that core questions have been shaded with different coloured backgrounds for different sections of the instrument, while supplementary questions are all white. This should help you to distinguish between the different categories of indicators. Please try to fill in all the core questions for each section before moving to the supplementary ones. Remember that we are only asking you to collect information that is already available and you are not expected to conduct any additional survey(s).

3. Prefilled data: the answers to some of the questions have been prefilled by WHO HQ. Where this is the case, please verify this information as it may not be up-to-date. If you find that any of the prefilled responses are not correct, please change the value and document the source and year.

4. Calculated fields: for a few items, you will not be required to enter any value as these will be generated at WHO HQ using data entered into related fields. These fields have been clearly marked in red – please do not input any data into them or change data that are already in this field. For example, the per capita expenditure on health will be automatically calculated once the total health expenditure and population are entered into the questionnaire. This system is intended to improve the quality of answers and avoid you having to perform additional calculations. Calculated fields are protected and cannot be changed.

5. Possible answers:

Checkbox 'Yes/No/Unknown': tick one of the three options (only one answer is possible).

Multiple choice checkbox: tick any of the options that apply (multiple answers are sometimes possible).

Percentage fields: 0-100. Please use decimal points ('dots') for decimals (example: 98.11). Please do not use ranges (e.g. "3-5"). If you only have ranges, then use the median and otherwise the mean. In this instance, please detail what data you have used and what the range is in the comment boxes.

Number fields: unlimited number. Please use decimal points ('dots') for decimals (example: 29387.93). Please do not use ranges. If you only have ranges, then use the median and otherwise the mean. In this instance, please detail what data you have used and what the range is in the comment boxes.

6. Comments: comments fields allow the entry of free text to clarify or follow up on answers given. Please reference each comment by using the number of the question you are referring to (example: 2.01.02).

7. Year of data : year fields should be used to specify the year of the **data** used to answer the question. Only values between 1930 and 2011 will be accepted. Please use this column as follows:

- When the source refers directly to a specific document (for example: 'Medicines Act' or 'EML'), please put in the publication year of the document (note: only the year and not a specific date can be entered).
- When the source refers to a document that contains older data than the document itself, please put in the original year of the data. For example, when the total population for 2008 is extracted from the World Health Statistics 2010, please put 2008 in the 'year' column and 'World Health Statistics 2010' in the 'source' column.
- When the source of the information is not a document, but the informant himself/herself, please put in the current year.

8. Source of data: sources used for the answers given will be referenced in the narrative country profile and in the databases in which the information will be stored. Please specify your sources as clearly as possible by providing the name, year, and writer/publisher of the documents used. Also provide a web (URL) link to the documents, if available. If there is only a non-English version of the reference available, then please include it regardless of the language. Use the 'source' column to enter the name and year of the **source**, and use the "Comments and References" fields at the end of every section to list the sources. In case the source is not documented, then provide the name and title of the person and/or the entity they work for as a source of information. Examples are given below.

7.01.12S	Which of the following tender methods are used in public sector procurement:		1996	DoH, 1996
7.01.12.01 S	National competitive tenders	Yes ☒ No ☐		
7.01.12.02 S	International competitive tenders	Yes ☒ No ☐		
7.01.12.03 S	Direct purchasing	Yes ☐ No ☐		
7.01.13S	Comments and References	National Drug Policy for South Africa , published in 1996. Document availabilt at: http://www.doh.gov.za/docs/policy/drugsjan1996.pdf		

9. Documents: you will see in the questionnaire that we would like you to collect and share a number of key country documents that we believe would greatly enrich the country's profile content and these documents could be made available through countries and WHO web pages. Please attach the following documents, if available:

- National Medicines Policy (NMP);
- NMP implementation plan;
- National Medicines Act;
- National pharmaceutical Human Resources report or strategic plan;
- Latest report on the national pharmaceutical market (any source);
- Pharmacovigilance national centre report (including an Adverse Drug Reaction (ADR), analysis report produced in the last two years);
- National pharmaceutical legislation or regulation;
- Annual report of quality control laboratories;

- Annual report of national regulatory authority;
- Legal provisions on medicines price regulations;
- Medicines procurement policy;
- National Essential Medicines List (EML);
- National Standard Treatment Guidelines (STGs);
- National strategy for antimicrobial resistance;
- Any other medicines pricing/availability surveys, household surveys and rational use surveys, in addition to the ones used to prefill the instrument.

The last page of the questionnaire contains a table with the list of key documents to be attached. Please fill it in by indicating the exact title, publisher and year for each attachment as shown in the example below.

Document	Exact title	Author	Publisher	Year	File name
Essential Medicines List	National Medicines List	Ministry of Health	Ministry of Health	2009	EML.doc
National Medicines Policy	National Drug Policy	Federal Ministry of Health	Federal Ministry of Health	2005	NDP.pdf

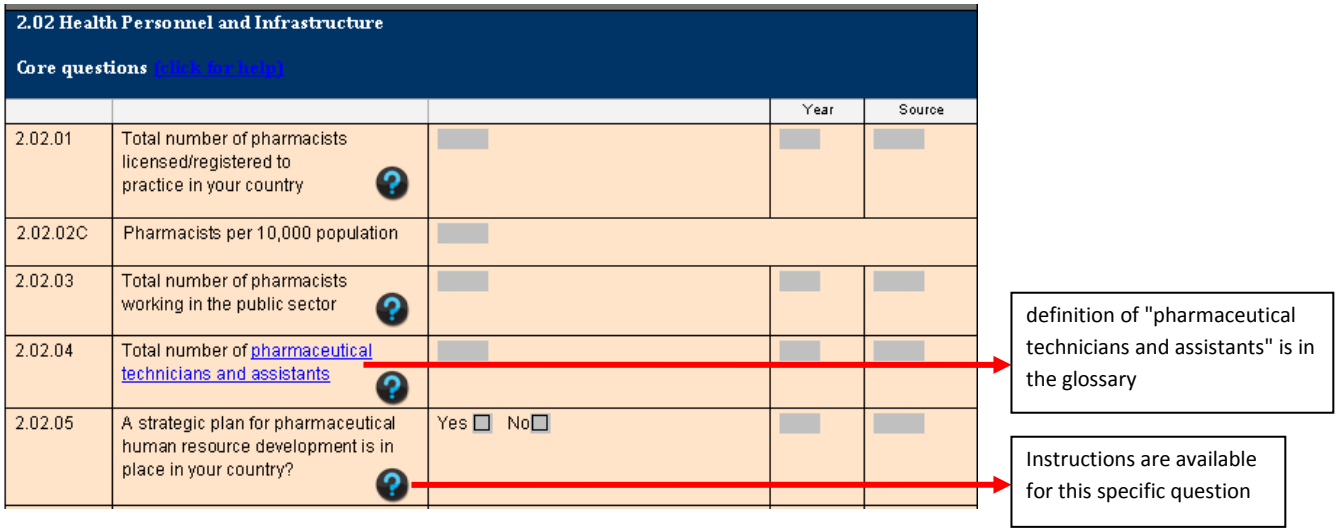
These documents will be published on the WHO web site's medicines library (http://apps.who.int/medicinedocs/en/) and will therefore have to be endorsed by the Ministry of Health prior to being made publicly available. You can send us these documents by e-mail as attachments or you can upload them into a protected web site. Please use the table at the end of the instrument to report the title, year and author of the documents attached.

10. Attaching files to the questionnaire: please place all files to be attached in a single folder on your computer. Name the documents as follows: <short name of the document>.doc (example: EML.doc). Then compress (ZIP) the files and attach the compressed file with the completed instrument to the email. If the total file size of the compressed file exceeds 7 MB, you can upload the documents in a protected file server called MedNet, which is managed by WHO. The procedure for doing this is very simple and please contact Mr Enrico Cinnella in WHO HQ, Geneva, (cinnellae@who.int) to be granted access to MedNet and to receive instructions on how to upload files. You can also upload documents to the WHO Medicines Documentation server at http://hinfo.humaninfo.ro/medicinedocs/, though the documents will only appear on the Medicines Documentation site at the beginning of the following month.

11. Manual for use of the questionnaire: the manual contains detailed instructions on the questionnaire, on where to find information and how to answer questions.

Questions that may be particularly problematic are marked with the following icon:

12. Glossary: the glossary contains definitions for all key and/or problematic items in the instrument. It is highly recommended that you use the glossary, since exact definitions might differ between countries and institutions. The glossary is at the end of the file. When a question contains an item that is defined in the glossary, the terms will be marked in bold, underlined and written in blue font.

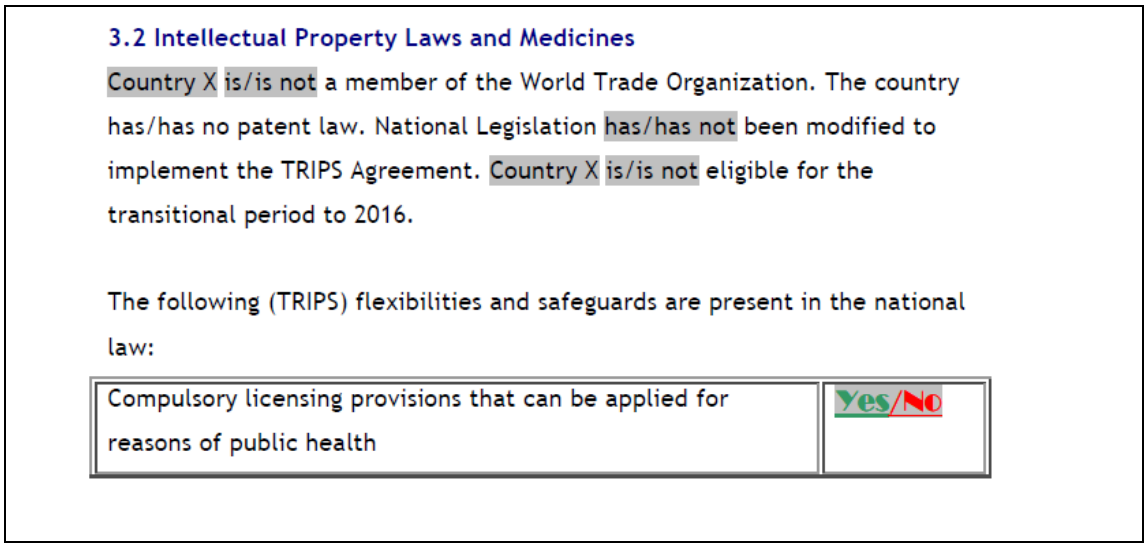


13. Respondents and acknowledgements: at the beginning of every section there are fields available to fill in details about the respondent for that particular section. It is also possible to enter the details of multiple respondents. At the end of the instrument please add a list of contributors who should be acknowledged. Provide their names and the main organization(s) they work for.

14. Endorsement of data: A formal endorsement needs to be signed by a senior official in the Ministry of Health before the completed questionnaire is sent back to WHO. The endorsement form is included in the pack of CD-ROM documents you have received from WHO. Please present the endorsement form to a senior official in the Ministry of Health for signature, and for obtaining permission to use and publish the data.

15. Process of creating a country profile document: The data you will collect using this questionnaire can be used to develop a pharmaceutical sector country profile for the country. Examples of profiles are available on-line at http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index1.html

WHO has prepared a template profile (included in the CD) that can be easily used by countries and that will help presenting data in the form of tables, graphs and charts. Countries can use the generic template provided by WHO and add the information in the questionnaire. Below you can find an example of the template that shows how fields can be changed according to the specific responses provided by each country.



3.2 Intellectual Property Laws and Medicines

Country X is/is not a member of the World Trade Organization. The country has/has no patent law. National Legislation has/has not been modified to implement the TRIPS Agreement. Country X is/is not eligible for the transitional period to 2016.

The following (TRIPS) flexibilities and safeguards are present in the national law:

Compulsory licensing provisions that can be applied for reasons of public health	Yes/No

In each section of the questionnaire you will find some comment boxes that you can use to expand on the answer to one or more questions. The text of these comments can also be included in the profile in order to present the country situation in more detail.

In the questionnaire you are also asked to indicate the source and date of each piece of information you provide; these should be used to develop bibliographic references for the profile.

If you prefer, WHO can develop the narrative profile and the Organization will then share the document with the country, which will own/maintain the copyright for it and will be able to publish it as a national document.

Section 0 General Info 0.01 Contact Info		
0.01.01	Country (precoded)	Iraq-RV
0.01.02	Name coordinator	Pharmacist Jamila Z. Lafta
0.01.03	Address (Street, City)	Baghdad, Iraq
0.01.04	Phone number	+964 790 194 5692
0.01.05	Email address	pharmacydepmoh@yahoo.com
0.01.06	Web address	http://moh.gov.iq/english/
0.01.07	Institution	MOH

Section 1 Health and Demographic data

1.00 Respondent Information Section 1

1.00.01	Name of person responsible for filling out Survey section 1	Dr. Imad abdulsalam abdulwahhab
1.00.02	Phone number	+ 964 790 192 5619, +964 790 182 8153
1.00.03	Email address	the_dr_imad@yahoo.com
1.00.04	Other respondents for filling out this section	Dr. Sanaa S. Majeed, Dr. May A. Salman, Dr.Ali M.Hassan, Dr.Anfal D. Aboulhab

1.01 Demographic and Socioeconomic Indicators

Core questions (click here for help)

			Year	Source
1.01.01	Population, total (,000)	32,326	2009	COSIT
1.01.02	Population growth rate (Annual %)	3.4	2009	MOH
1.01.03	Total Gross Domestic Product (GDP) (millions US$)	65,837	2009	World Bank data
1.01.04	GDP growth (Annual %)	4.20	2009	World Bank data
1.01.05C	GDP per capita (US$ current exchange rate)	2.036	2009	World Bank data, COSIT
1.01.06	Comments and References	1.01.01 COSIT is the "Central Organization for Statistics and Information Technology" 1.01.02 Annual report 2009/Directorate of Planning & Human resource development/MOH. The figure above (3.4%) does not include Kurdistan regionional Goverment (KRG)		

Supplementary questions (click here for help)

			Year	Source
1.01.07S	Population < 15 years (% of total population)	43.1	2009	COSIT

1.01.08S	Population > 60 years (% of total population)	4.34	2009	COSIT
1.01.09S	Urban population (% of total population)	66.62	2009	COSIT
1.01.10S	Fertility rate, total (Births per woman)	4.9	2009	MOH
1.01.11S	Population living with less than $1.25/day (international PPP) (%)			
1.01.12S	Population living below nationally defined poverty line (%)			
1.01.13S	Income share held by lowest 20% of the population (% of national income)			
1.01.14S	Adult literacy rate, 15+ years (% of relevant population)	74	2008	WHS
1.01.15S	Comments and References	1.01.10S Annual report 2009/Directorate of Planning & Human resource development/MOH		

1.02 Mortality and Causes of Death

Core questions (click here for help)

			Year	Source
1.02.01	Life expectancy at birth for men (Years)	69	2009	MOH & KRG Moh
1.02.02	Life expectancy at birth for women (Years)	74	2009	MOH & KRG Moh
1.02.03	Infant mortality rate, between birth and age 1 (/1,000 live births)	24	2009	MOH
1.02.04	Under 5 mortality rate (/1,000 live births)	29.5	2009	WHS
1.02.05	Maternal mortality ratio (/100,000 live births)	32	2009	MOH

1.02.06	Please provide a list of top 10 diseases causing mortality		2009	MOH
1.02.06.01	Disease 1	Heart Failure		
1.02.06.02	Disease 2	Cerebrovasecular Disease		
1.02.06.03	Disease 3	External Forces Causing Death		
1.02.06.04	Disease 4	Ischemic heart disease		
1.02.06.05	Disease 5	Renal Failure		
1.02.06.06	Disease 6	Septeciemia		
1.02.06.07	Disease 7	Respiratory Distress Syndrom		
1.02.06.08	Disease 8	Senility		
1.02.06.09	Disease 9	Diabetus Mellutis		
1.02.06.10	Disease 10	Malignant Tumour of G.I.T		
1.02.07	Please provide a list of top 10 diseases causing morbidity		2009	MOH
1.02.07.01	Disease 1	Gastroenteritis		
1.02.07.02	Disease 2	Bronchitis		
1.02.07.03	Disease 3	Pneumonia		
1.02.07.04	Disease 4	Cardiovascular Disease		
1.02.07.05	Disease 5	Urinary System Disorders		
1.02.07.06	Disease 6	Abortion		
1.02.07.07	Disease 7	Measles		
1.02.07.08	Disease 8	Hernia		
1.02.07.09	Disease 9	Respiratory Distress Syndrom		

1.02.07.10	Disease 10	Diabetes Mellitus		
1.02.08	Comments and References	MOH/Directorate of Planning & Human resource development		
Supplementary questions (click here for help)				
			Year	Source
1.02.09S	Adult mortality rate for both sexes between 15 and 60 years (/1,000 population)	222	2009	WHS
1.02.10S	Neonatal mortality rate (/1,000 live births)	36	2009	MOH
1.02.11S	Age-standardized mortality rate by non-communicable diseases (/100,000 population)			
1.02.12S	Age-standardized mortality rate by cardiovascular diseases (/100,000 population)			
1.02.13S	Age-standardized mortality rate by cancer (/100,000 population)			
1.02.14S	Mortality rate for HIV/AIDS (/100,000 population)	0.002	2009	MOH
1.02.15S	Mortality rate for tuberculosis (/100,000 population)	0.2	2009	MOH
1.02.16S	Mortality rate for Malaria (/100,000 population)	0.0	2006	WHS
1.02.17S	Comments and References	MOH source is Annual report/Directorate of Planning & Human resource development/MOH		

Section 2 Health Services

2.00 Respondent Information Section 2

2.00.01	Name of person responsible for filling out this section of the instrument	Dr.Khalid Razzaq Hasan
2.00.02	Phone number	+ 964 790 135 5489
2.00.03	Email address	k_aljanabi2001@yahoo.com
2.00.04	Other respondents for filling out this section	

2.01 Health Expenditures

Core questions (click here for help)

			Year	Source
2.01.01.01	Total annual expenditure on health (millions NCU)	5,138,643	2008	NHA data
2.01.01.02	Total annual expenditure on health (millions US$ average exchange rate)	4,392	2008	NHA data
2.01.02C	Total health expenditure as % of Gross Domestic Product	3.9		
2.01.03.01C	Total annual expenditure on health per capita (NCU)	158,963		
2.01.03.02C	Total annual expenditure on health per capita (US$ average exchange rate)	136		
2.01.04.01	General government annual expenditure on health (millions NCU)	3,760,586	2008	NHA data
2.01.04.02	General government annual expenditure on health (millions US$ average exchange rate)	3,214	2008	NHA data
2.01.05	Government annual expenditure on health as percentage of total government budget (% of total	3.06	2008	NHA data

	government budget)			
2.01.06C	Government annual expenditure on health as % of total expenditure on health (% of total expenditure on health)	73.18	2008	NHA data
2.01.07.01C	Annual per capita government expenditure on health (NCU)	116,333		
2.01.07.02C	Annual per capita government expenditure on health (US$ average exchange rate)	99.43		
2.01.08C	Private health expenditure as % of total health expenditure (% of total expenditure on health)	26.82	2008	NHA data
2.01.09	Population covered by a public health service or public health insurance or social health insurance, or other sickness funds of total population)	100	2010	MOH
2.01.10	Population covered by private health insurance (% of total population)			
2.01.11.01	Total pharmaceutical expenditure (millions NCU)	1,892,415	2008	NHA
2.01.11.02	Total pharmaceutical expenditure (millions US$ current exchange rate)	1,617	2008	NHA
2.01.12.01C	Total pharmaceutical expenditure per capita (NCU)	58,541		
2.01.12.02C	Total pharmaceutical expenditure per capita (US$ current exchange rate)	50		
2.01.13C	Pharmaceutical expenditure as a % of GDP (% of GDP)	2.46		
2.01.14C	Pharmaceutical expenditure as a % of Health Expenditure (% of total health expenditure)	36.8		

2.01.15.01	Total public expenditure on pharmaceuticals (millions NCU)	1,365,298	2008	NHA
2.01.15.02	Total public expenditure on pharmaceuticals (millions US$ current exchange rate)	1,166	2008	NHA
2.01.16C	Share of public expenditure on pharmaceuticals as percentage of total expenditure on pharmaceuticals (%)	72.10	2008	NHA
2.01.17.01C	Total public expenditure on pharmaceuticals per capita (NCU)	42,235		
2.01.17.02C	Total public expenditure on pharmaceuticals per capita (US$ current exchange rate)	36		
2.01.18.01	Total private expenditure on pharmaceuticals (millions NCU)	527,117	2008	NHA
2.01.18.02	Total private expenditure on pharmaceuticals (millions US$ current exchange rate)	450	2008	NHA
2.01.19	Comments and References	Exchange rate: 1 US $ = 1,170 Iraqi Dinars (ID) 2.01.10 unkown		

Supplementary questions (click for help)

			Year	Source
2.01.20S	Social security expenditure as % of government expenditure on health (% of government expenditure on health)	0.0	2008	NHA data
2.01.21S	Market share of generic pharmaceuticals [branded and INN] by value (%)	not available		MOH
2.01.22S	Annual growth rate of total pharmaceuticals market value (%)	not available		MOH
2.01.23S	Annual growth rate of generic pharmaceuticals market	not available		MOH

	value (%)			
2.01.24S	Private out-of-pocket expenditure as % of private health expenditure (% of private expenditure on health)	100.00	2008	NHA data
2.01.25S	Premiums for private prepaid health plans as % of total private health expenditure (% of private expenditure on health)	0.00	2008	NHA data
2.01.26S	Comments and References	2.01.24s There is no private insurance in Iraq yet		

2.02 Health Personnel and Infrastructure

Core questions (click for help)

			Year	Source
2.02.01	Total number of pharmacists licensed/registered to practice in your country	11,206	2007	MOH
2.02.02C	Pharmacists per 10,000 population	3.47		
2.02.03	Total number of pharmacists working in the public sector	5,376	2009	MOH
2.02.04	Total number of pharmaceutical technicians and assistants	5,910	2009	MOH
2.02.05	A strategic plan for pharmaceutical human resource development is in place in your country?	Yes ☒ No ☐	2010	MOH
2.02.06	Total number of physicians	22,396	2009	MOH
2.02.07C	Physicians per 10,000 pop	6.93		
2.02.08	Total number of nursing and midwifery personnel	44,201	2009	MOH
2.02.09C	Nurses and midwives per 10,000 pop	10.56		

2.02.10	Total number of hospitals	220	2009	MOH
2.02.11	Number of hospital beds per 10,000 pop	13	2009	WHS
2.02.12	Total number of primary health care units and centers	2168	2009	MOH
2.02.13	Total number of licensed pharmacies	9,500	2010	iraqi pharmaceutical syndicante
2.02.14	Comments and References			

Supplementary questions (click here for help)

			Year	Source
2.02.15S	Starting annual salary for a newly registered pharmacist in the public sector (NCU)	362,000	2011	MOH
2.02.16S	Total number of pharmacists who graduated (first degree) in the past 2 years in your country	1,089	2010	MOH
2.02.17S	Are there accreditation requirements for pharmacy schools?	Yes ☒ No☐	2011	Dean of Pharmacy Collage/ University of Baghdad
2.02.18S	Is the Pharmacy Curriculum regularly reviewed?	Yes ☒ No ☐	2011	Dean of Pharmacy Collage/ University of Baghdad
2.02.19S	Comments and References	2.02.15S: 362000 ID		

Section 3 Policy issues

3.00 Respondent Information Section 4

3.00.01	Name of person responsible for filling out this section of the instrument	Pharmacist Jamila Z. Lafta		
3.00.02	Phone number	+964 790 194 5692		
3.00.03	Email address	pharmacydepmoh@yahoo.com		
3.00.04	Other respondents for filling out this section			

3.01 Policy Framework

Core questions (click here for help)

			Year	Source
3.01.01	National Health Policy exists. If yes, please write year of the most recent document in the "year" field.	Yes ☐ No ☒		MOH
3.01.02	National Health Policy Implementation plan exists. If yes, please write the year of the most recent document in the "year"	Yes ☐ No ☒		MOH
3.01.03	Please provide comments on the Health policy and its implementation plan			
3.01.04	National Medicines Policy official document exists. If yes, please write the year of the most recent document in the "year" field.	Yes ☒ No ☐	2008	MOH
3.01.05	Group of policies addressing pharmaceuticals exist.	Yes ☒ No ☐	2010	MOH
3.01.06	National Medicines Policy covers the following components:	—		

3.01.06.01	Selection of Essential Medicines	☒Yes		
3.01.06.02	Medicines Financing	☒Yes		
3.01.06.03	Medicines Pricing	☒Yes		
3.01.06.04	Medicines Procurement	☒Yes		
3.01.06.05	Medicines Distribution	☒Yes		
3.01.06.06	Medicines Regulation	☒Yes		
3.01.06.07	Pharmacovigilance	☒Yes		
3.01.06.08	Rational Use of Medicines	☒Yes		
3.01.06.09	Human Resource Development	☒Yes		
3.01.06.10	Research	☒Yes		
3.01.06.11	Monitoring and Evaluation	☒Yes		
3.01.06.12	Traditional Medicine	☒Yes		
3.01.07	National medicines policy implementation plan exists. If yes, please write year of the most recent document.	Yes ☐ No ☒		
3.01.08	Policy or group of policies on clinical laboratories exist. If yes, please write year of the most recent document in the "year" field	Yes ☒ No ☐	2011	MOH
3.01.09	National clinical laboratory policy implementation plan exists. If yes, please write year of the most recent document in the "year" field	Yes ☒ No ☐	2011	MOH
3.01.10	Access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution or national legislation?	Yes ☒ No ☐	2005	IRAQI constitution 2005

3.01.11	There are official written guidelines on medicines donations.	Yes ☒ No ☐	2008	MOH
3.01.12	Is pharmaceutical policy implementation being regularly monitored/assessed?	Yes ☐ No ☒		
3.01.12.01	Who is responsible for pharmaceutical policy monitoring?			
3.01.13	Is there a national good governance policy?	Yes ☐ No ☒		
3.01.13.01	Multisectoral	☐Yes		
3.01.13.02	For the pharmaceutical sector	☐Yes		
3.01.13.03	Which agencies are responsible?			
3.01.14	A policy is in place to manage and sanction conflict of interest issues in pharmaceutical affairs.	Yes ☒ No ☐		
3.01.15	There is a formal code of conduct for public officials.	Yes ☐ No ☒		
3.01.16	Is there a whistle-blowing mechanism allowing individuals to raise a concern about wrongdoing occurring in the pharmaceutical sector of your country (ombudsperson)?	Yes ☒ No ☐	2010	moh
3.01.16.01	Please describe:	By using special forms that sent to iraqi pharmacovigilance & general inspector office		
3.01.17	Comments and References	3.01.01(there is no document but policy is implemented through menisteril instructions & orderes) 3.01.08(POLICY REGARDING LABROTORIES UPDATED ANNUALY). 3.01.14(there is a managerial & ministerial instructions only) 3.01.13 and 3.01.12.02 MOH Iraq has joined the WHO GGM programme in December 2012. Currently implementing phase one.		

Section 4 Medicines Trade and Production

4.00 Respondent Information Section 4

4.00.01	Name of person responsible for filling out this section of the instrument	Pharmacist Jamila Z. Lafta
4.00.02	Phone number	+964 790 194 5692
4.00.03	Email address	pharmacydepmoh@yaho.com
4.00.04	Other respondents for filling out this section	

4.01 Intellectual Property Laws and Medicines

Core questions (click here for help)

			Year	Source
4.01.01	Country is a member of the World Trade Organization	Yes ☐ No☒		WTO
4.01.02	Legal provisions provide for granting of Patents on:			
4.01.02.01	Pharmaceuticals	Yes ☒ No☐		
4.01.02.02	Laboratory supplies	Yes ☒ No ☐		
4.01.02.03	Medical supplies	Yes ☒ No ☐		
4.01.02.04	Medical equipment	Yes ☒ No ☐		
4.01.03.01	Please provide name and address of the institution responsible for managing and enforcing intellectual property rights	Ministry of Planning/Central Organization for Standardization and Quality control		
4.01.03.02	Please provide URL			
4.01.04	National Legislation has been modified to implement the TRIPS Agreement	Yes ☐ No ☒		MOH

4.01.05	Current laws contain (TRIPS) flexibilities and safeguards	Yes ☐ No☒		MOH
4.01.06	Country is eligible for the transitional period to 2016	Yes ☐ No☒		MOH
4.01.07	Which of the following (TRIPS) flexibilities and safeguards are present in the national law?			
4.01.07.01	Compulsory licensing provisions that can be applied for reasons of public health	Yes ☐ No ☒		
4.01.07.02	Bolar exception	Yes ☐ No ☒		
4.01.08	Are parallel importing provisions present in the national law?	Yes ☐ No ☒		MOH
4.01.09	The country is engaged in initiatives to strengthen capacity to manage and apply intellectual property rights to contribute to innovation and promote public health	Yes ☐ No ☒		MOH
4.01.10	Are there legal provisions for data exclusivity for pharmaceuticals	Yes ☐ No ☒		MOH
4.01.11	Legal provisions exist for patent extension	Yes ☒ No ☐	2000	*
4.01.12	Legal provisions exist for linkage between patent status and Marketing Authorization	Yes ☒ No ☐	2000	*
4.01.13	Comments and References	4.01.11&12 (Ministry of Planning/ Central office for Standardization & Qulality control/Law of patent & industerial samples no.56 at 2000)		

4.02 Manufacturing

Core questions (click here for help)

			Year	Source
4.02.01	Number of licensed pharmaceutical	23	2011	MOH

	manufacturers in the country			
4.02.02	Country has manufacturing capacity			
4.02.02.01	R&D to discover new active substances	Yes ☐ No ☒ Unknown ☐		
4.02.02.02	Production of pharmaceutical starting materials (APIs)	Yes ☐ No ☒ Unknown ☐		
4.02.02.03	Production of formulations from pharmaceutical starting material	Yes ☒ No ☐ Unknown ☐		
4.02.02.04	Repackaging of finished dosage forms	Yes ☐ No ☒ Unknown ☐		
4.02.03	Percentage of market share by value produced by domestic manufacturers (%)	not available		MOH
4.02.04	Comments and References			

Supplementary questions (click here for help)

			Year	Source
4.02.05S	Percentage of market share by volume produced by domestic manufacturers (%)	not available		
4.02.06S	Number of multinational pharmaceutical companies manufacturing medicines locally	0	2010	MOH
4.02.07S	Number of manufacturers that are Good Manufacturing Practice (GMP) certified	18	2011	MOH
4.02.08S	Comments and References			

Section 5 Medicines Regulation

5.00 Respondent Information Section 4

5.00.01	Name of person responsible for filling out this section of the instrument	pharmacist Jamila Z. Lafta
5.00.02	Phone number	+964 790 194 5692
5.00.03	Email address	pharmacydepmoh@yaho.com
5.00.04	Other respondents for filling out this section	Pharmacist Jinan J. Abdulrazzak

5.01 Regulatory Framework

Core questions (click here for help)

			Year	Source
5.01.01	Are there legal provisions establishing the powers and responsibilities of the Medicines Regulatory Authority (MRA)?	Yes ☐ No ☒		MOH
5.01.02	There is a Medicines Regulatory Authority	Yes ☒ No ☐		MOH
5.01.03	If yes, please provide name and address of the Medicines regulatory authority	Directorate of technical Affair/Ministry of Health KIMADIA Iraqi Sundicate of pharmacists		
5.01.04	The Medicines Regulatory Authority is:			
5.01.04.01	Part of MoH	☒Yes		
5.01.04.02	Semi autonomous agency	☐Yes		
5.01.04.03	Other (please specify)			
5.01.05	What are the functions of the National Medicines Regulatory Authority?			

5.01.05.01	Marketing authorization / registration	Yes ☒ No ☐		
5.01.05.02	Inspection	Yes ☒ No ☐		
5.01.05.03	Import control	Yes ☒ No ☐		
5.01.05.04	Licensing	Yes ☒ No ☐		
5.01.05.05	Market control	Yes ☒ No ☐		
5.01.05.06	Quality control	Yes ☒ No ☐		
5.01.05.07	Medicines advertising and promotion	Yes ☒ No ☐		
5.01.05.08	Clinical trials control	Yes ☒ No ☐		
5.01.05.09	Pharmacovigilance	Yes ☒ No ☐		
5.01.05.10	Other: (please explain)			
5.01.06	Number of the MRA permanent staff		2011	moh
5.01.06.01	Date of response	26/6/2011		
5.01.07	The MRA has its own website	Yes ☒ No ☐	2011	moh
5.01.07.01	- If yes, please provide MRA Web site address (URL)	www.techmoh.net		
5.01.08	The MRA receives external technical assistance	Yes ☒ No ☐	2011	moh
5.01.08.01	If yes, please describe:	WHO Iraq Country Office provides external technical assistance at different regulatory functions(quality control, registration, GMP)		
5.01.09	The MRA is involved in harmonization/ collaboration initiatives	Yes ☐ No ☒	2007	MOH
5.01.09.01	- If yes, please specify			
5.01.10	An assessment of the medicines regulatory system has been conducted in the last five years.	Yes ☐ No ☒	2010	MOH
5.01.11	Medicines Regulatory Authority gets funds from regular budget of the	Yes ☒ No ☐	2007	MOH

	government.			
5.01.12	Medicines Regulatory Authority is funded from fees for services provided.	Yes ☐ No ☒	2011	MOH
5.01.13	Medicines Regulatory Authority receives funds/support from other sources	Yes ☒ No ☐	2011	MOH
5.01.13.01	- If yes, please specify	FROM WHO		
5.01.14	Revenues derived from regulatory activities are kept with the Regulatory Authority	Yes ☐ No ☒	2011	MOH
5.01.15	The Regulatory Authority is using a computerized information management system to store and retrieve information on registration, inspections, etc.	Yes ☒ No ☐	2011	MOH
5.01.16	Comments and References	5.01.01 and 5.01.02 There is no Law or act that provides power and responsibilities to a MRA in Iraq. there are ministirial orders, laws here and there, but not one clear document that regulates the work of a MRA. The Directorite of Technical Affairs in the Ministry of Health in addition to the state owned public pharmaceutical procurment and distribution company (KIMADIA) and the Syndicate of Pharmacy play the role of a MRA.		

5.02 Marketing Authorization (Registration)

Core questions (click here for help)

			Year	Source
5.02.01	Legal provisions require a Marketing Authorization (registration) for all pharmaceutical products on the market	Yes ☒ No ☐	2011	MOH
5.02.02	Are there any mechanism for exception/waiver of registration?	Yes ☒ No ☐	2011	MOH

5.02.03	Are there mechanisms for recognition of registration done by other countries	Yes ☐ No ☒	2011	MOH
5.02.03.01	If yes, please explain:			
5.02.04	Explicit and publicly available criteria exist for assessing applications for Marketing Authorization of pharmaceutical products	Yes ☒ No ☐	2011	moh
5.02.05	Information from the prequalification programme managed by WHO is used for product registration	Yes ☐ No ☒	2011	moh
5.02.06	Number of pharmaceutical products registered in your country	7,000	2011	moh
5.02.07	Legal provisions require the MRA to make the list of registered pharmaceuticals with defined periodicity publicly available	Yes ☒ No ☐	2007	MOH
5.02.07.01	If yes, how frequently updated	monthly		
5.02.07.02	If yes, please provide updated list or URL *			
5.02.08	Medicines registration always includes the INN (International Non-proprietary Names)	Yes ☐ No ☒	2007	MOH
5.02.09	Legal provisions require the payment of a fee for Medicines Marketing Authorization (registration) applications	Yes ☒ No ☐	2011	moh
5.02.10	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
5.02.11S	Legal provisions require Marketing Authorization holders to provide information about variations to the	Yes ☒ No ☐	2011	moh

	existing Marketing Authorization			
5.02.12S	Legal provisions require publication of a Summary of Product Characteristics (SPCs) of the medicines registered	Yes ☒ No ☐	2011	moh
5.02.13S	Legal provisions require the establishment of an expert committee involved in the marketing authorization process	Yes ☐ No ☒	2007	MOH
5.02.14S	Certificate for Pharmaceutical Products in accordance with the WHO Certification scheme is required as part of the Marketing Authorization application	Yes ☒ No ☐	2011	MOH
5.02.15S	Legal provisions require declaration of potential conflict of interests for the experts involved in the assessment and decision-making for registration	Yes ☒ No ☐	2011	MOH
5.02.16S	Legal provisions allow applicants to appeal against MRAs decisions	Yes ☒ No ☐	2011	MOH
5.02.17S	Registration fee - the amount per application for pharmaceutical product containing New Chemical Entity (NCE) (US$)	165	2011	MOH
5.02.18S	Registration fee - the Amount per application for a generic pharmaceutical product (US$)	165	2011	MOH
5.02.19S	Time limit for the assessment of a Marketing Authorization application (months)		2011	MOH
5.02.20S	Comments & References			

5.03 Regulatory Inspection

Core Questions(click here for help)

			Year	Source
5.03.01	Legal provisions exist allowing for appointment of government pharmaceutical inspectors	Yes ☒ No ☐	1970	law of practicing pharmacy
5.03.02	Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed	Yes ☒ No ☐	2007	MOH
5.03.02.01	If yes, legal provisions exist requiring inspections to be performed	Yes ☒ No ☐		
5.03.03	Inspection is a pre-requisite for licensing of:			
5.03.03.01	Public facilities	Yes ☒ No ☐		
5.03.03.02	Private facilities	Yes ☒ No ☐		
5.03.04	Inspection requirements are the same for public and private facilities	Yes ☐ No ☒		
5.03.05.01	Local manufactures are inspected for GMP compliance	Yes ☒ No ☐	2007	MOH
5.03.05.02	Private wholesalers are inspected	Yes ☒ No ☐		
5.03.05.03	Retail distributors are inspected	Yes ☒ No ☐		
5.03.05.04	Public pharmacies and stores are inspected	Yes ☒ No ☐		
5.03.05.05	Pharmacies and dispensing points of health facilities are inspected	Yes ☒ No ☐		
5.03.05.06	Please provide details on frequency of inspections for the different categories of facilities	frequently		
5.03.06	Comments and References			

5.04 Import Control

Core Questions (click here for help)				
			Year	Source
5.04.01	Legal provisions exist requiring authorization to import medicines	Yes ☒ No ☐	1998	Official Regulation no 60/MOH
5.04.02	Legal provisions exist allowing the sampling of imported products for testing	Yes ☒ No ☐	1981	Law of public health+Official regulation no 2 year 2001/MOH
5.04.03	Legal provisions exist requiring importation of medicines through authorized ports of entry	Yes ☒ No ☐	2008	Instruction/ MOH
5.04.04	Legal provisions exist allowing inspection of imported pharmaceutical products at the authorized ports of entry	Yes ☒ No ☐	2008	menistrial instruction
5.04.05	Comments and References			
5.05 Licensing				
			Year	Source
5.05.01	Legal provisions exist requiring manufacturers to be licensed	Yes ☒ No ☐	2007	MOH
5.05.02	Legal provisions exist requiring both domestic and international manufacturers to comply with Good manufacturing Practices (GMP)	Yes ☒ No ☐		
5.05.02.01	If no, please explain			
5.05.03	GMP requirements are published by the government.	Yes ☐ No ☒		
5.05.04	Legal provisions exist requiring importers to be licensed	Yes ☒ No ☐	2007	MOH

5.05.05	Legal provisions exist requiring wholesalers and distributors to be licensed	Yes ☒ No ☐	2007	MOH
5.05.06	Legal provisions exist requiring wholesalers and distributors to comply with Good Distributing Practices **When filling in this part, please also fill in the relevant questions in the procurement and distribution section (Section 7)**	Yes ☐ No ☒		
5.05.07	National Good Distribution Practice requirements are published by the government	Yes ☐ No ☒		MOH
5.05.08	Legal provisions exist requiring pharmacists to be registered	Yes ☒ No ☐	1970	law of practicing pharmacy
5.05.09	Legal provisions exists requiring private pharmacies to be licensed	Yes ☒ No ☐	1970	law of practicing pharmacy
5.05.10	Legal provision exist requiring public pharmacies to be licensed	Yes ☒ No ☐	1970	law of practicing pharmacy
5.05.11	National Good Pharmacy Practice Guidelines are published by the government	Yes ☒ No ☐	2010	MENISTRIAL INSTRUCTION & BOOKLET FOR GOOD PHARMACY PRACTICE MOH 2010
5.05.12	Legal provisions require the publication of a list of all licensed pharmaceutical facilities	Yes ☒ No ☐	1970	law of practicing pharmacy

5.05.13	Comments and References			
5.06 Market Control and Quality Control **Core Questions (click here for help)**				
			Year	Source
5.06.01	Legal Provisions for regulating the pharmaceutical market exist	Yes ☒ No ☐	2011	continueous menstirial instruction &law of practicing pharmacy
5.06.02	Does a laboratory exist in the country for Quality Control testing?	Yes ☒ No ☐		
5.06.02.01	If yes, is the laboratory part of the MRA?	Yes ☐ No ☒		
5.06.02.02	Does the regulatory authority contract services elsewhere?	Yes ☐ No ☒		
5.06.02.03	If yes, please describe			
5.06.03	Is there any national laboratory accepted for collaboration with WHO prequalification Programme? Please describe.			
5.06.04	Medicines are tested:		2010	moh
5.06.04.01	For quality monitoring in the public sector (routine sampling in pharmacy stores and health facilities)	Yes ☐ No ☒		
5.06.04.02	For quality monitoring in private sector (routine sampling in retail outlets)	Yes ☒ No ☐		
5.06.04.03	When there are complaints or problem reports	Yes ☒ No ☐		

5.06.04.04	For product registration	Yes ☒ No ☐		
5.06.04.05	For public procurement prequalification	Yes ☐ No ☒		
5.06.04.06	For public program products prior to acceptance and/or distribution	Yes ☒ No ☐		
5.06.05	Samples are collected by government inspectors for undertaking post-marketing surveillance testing	Yes ☒ No ☐	2007	MOH
5.06.06	How many Quality Control samples were taken for testing in the last two years?	12000	2010	moh
5.06.07	Total number of samples tested in the last two years that failed to meet quality standards	0		
5.06.08	Results of quality testing in past two years are publicly available	Yes ☒ No ☐	2011	moh
5.06.09	Comments and References			

5.07 Medicines Advertising and Promotion

Core Questions (click here for help)

			Year	Source
5.07.01	Legal provisions exist to control the promotion and/or advertising of prescription medicines	Yes ☒ No ☐	1970	law of practicing pharmacy
5.07.02	Who is responsible for regulating, promotion and/or advertising of medicines? Please describe:	MOH		
5.07.03	Legal provisions prohibit direct advertising of prescription medicines to the public	Yes ☒ No ☐	1970	law of practicing pharmacy
5.07.04	Legal provisions require a pre-approval for medicines advertisements and promotional	Yes ☐ No ☒		moh

	materials			
5.07.05	Guidelines/Regulations exist for advertising and promotion of non-prescription medicines	Yes ☐ No ☒		moh
5.07.06	A national code of conduct exists concerning advertising and promotion of medicines by marketing authorization holders and is publicly available	Yes ☐ No ☒		moh
5.07.06.01	If yes, the code of conduct applies to domestic manufacturers only, multinational manufacturers only, or both			
	Domestic only	☐Yes		
	Multinational only	☐Yes		
	Both	☐Yes		
5.07.06.02	If yes, adherence to the code is voluntary	Yes ☐ No ☐		
5.07.06.03	If yes, the code contains a formal process for complaints and sanctions	Yes ☐ No ☐		
5.07.06.04	If yes, list of complaints and sanctions for the last two years is publicly available	Yes ☐ No ☐		
5.07.07	Comments and References			

5.08 Clinical trials

Core Questions (click here for help)

			Year	Source
5.08.01	Legal provisions exist requiring authorization for conducting Clinical Trials by the MRA	Yes ☒ No ☐	2001	law of public healt+offici

				al regulation no 8/moh
5.08.02	Legal provisions exist requiring the agreement by an ethics committee/ institutional review board of the Clinical Trials to be performed	Yes ☐ No ☒		moh
5.08.03	Legal provisions exist requiring registration of the clinical trials into international/national/regional registry	Yes ☒ No ☐	2001	law of public healt+official regulation no 8/moh
5.08.04	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
5.08.05S	Legal provisions exist for GMP compliance of investigational products	Yes ☒ No ☐	2001	Law of public healt+official regulation no 8/moh
5.08.06S	Legal provisions require sponsor, investigator to comply with Good Clinical Practices (GCP)	Yes ☒ No ☐	2001	Law of public healt+official regulation no 8/moh
5.08.07S	National GCP regulations are published by the Government.	Yes ☐ No ☒		moh
5.08.08S	Legal provisions permit inspection of facilities where clinical trials are performed	Yes ☒ No ☐	2001	aw of public healt+official regulation no 8/moh
5.08.09S	Comments and References			

5.09 Controlled Medicines

Core Questions (click here for help)

			Date	Source
5.09.01	The country has adopted the following conventions:			
5.09.01.01	Single Convention on Narcotic Drugs, 1961	Yes ☒ No ☐	1962	International Narcotics Control Board
5.09.01.02	The 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	Yes ☒ No ☐	1978	International Narcotics Control Board
5.09.01.03	Convention on Psychotropic Substances 1971	Yes ☒ No ☐	1976	International Narcotics Control Board
5.09.01.04	United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	Yes ☒ No ☐	1998	International Narcotics Control Board
5.09.02	Laws for the control of narcotic and psychotropic substances, and precursors exist	Yes ☒ No ☐	1965	law no: 68
5.09.03	Annual consumption of Morphine (mg/capita)	0.250000	2011	International Narcotics Control Board
5.09.04	Comments and References			

Supplementary questions (click here for help)

			Year	Source
5.09.05S	The legal provisions and regulations for the control of narcotic and psychotropic substances, and precursors have been reviewed by a	Yes ☐ No ☐ Unknown ☒		

	WHO International Expert or Partner Organization to assess the balance between the prevention of abuse and access for medical need			
5.09.05.01S	If yes, year of review			
5.09.06S	Annual consumption of Fentanyl (mg/capita)	0.003125	2011	International Narcotics Control Board
5.09.07S	Annual consumption of Pethidine (mg/capita)	2.03125	2011	International Narcotics Control Board
5.09.08S	Annual consumption of Oxycodone (mg/capita)	0.00125	2011	INCB
5.09.09S	Annual consumption of Hydrocodone (mg/capita)		2011	INCB
5.09.10S	Annual consumption of Phenobarbital (mg/capita)	8	2010	International Narcotics Control Board
5.09.11S	Annual consumption of Methadone (mg/capita)			
5.09.12S	Comments and References			

5.10 Pharmacovigilance

Core Questions (click here for help)

			Year	Source
5.10.01	There are legal provision in the Medicines Act that provides for pharmacovigilance activities as part of the MRA mandate	Yes ☐ No ☒		moh
5.10.02	Legal provisions exist requiring the Marketing Authorization holder to continuously monitor the safety of	Yes ☐ No ☒		moh

	their products and report to the MRA			
5.10.03	Legal provisions about monitoring Adverse Drug Reactions (ADR) exist in your country	Yes ☐ No ☒		moh
5.10.04	A national pharmacovigilance centre linked to the MRA exists in your country	Yes ☒ No ☐	2011	moh
5.10.04.01	If a national pharmacovigilance centre exists in your country, how many staff does it employ full-time	4		
5.10.04.02	If a national pharmacovigilance center exists in your country, an analysis report has been published in the last two years.	Yes ☐ No ☒		
5.10.04.03	If a national pharmacovigilance center exists in your country, it publishes an ADR bulletin	Yes ☐ No ☒		
5.10.05	An official standardized form for reporting ADRs is used in your country	Yes ☒ No ☐	2011	moh
5.10.06	A national Adverse Drug Reactions database exists in your country	Yes ☒ No ☐	2011	moh
5.10.07	How many ADR reports are in the database?	40	2011	moh
5.10.08	How many reports have been submitted in the last two years?	40	2011	moh
5.10.09	Are ADR reports sent to the WHO database in Uppsala?	Yes ☒ No ☐	2011	moh
5.10.09.01	If yes, number of reports sent in the last two years	23	2011	moh
5.10.10	Is there a national ADR or pharmacovigilance advisory committee able to provide technical assistance on causality assessment,	Yes ☒ No ☐	2011	moh

	risk assessment, risk management, case investigation and, where necessary, crisis management including crisis communication?			
5.10.11	Is there a clear communication strategy for routine communication and crises communication?	Yes ☐ No ☒		
5.10.12	In the absence of a national pharmacovigilance system, ADRs are monitored in at least one public health program (for example TB, HIV, AIDS)?	Yes ☒ No ☐		
5.10.13	Please describe how you intend to enhance the Pharmacovigilance system	1- Regenerating a pharmacovigilance law 2- Regenerating a guidelines specially for Iraq 3- Regenerating a training package for Iraq		
5.10.14	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
5.10.15S	Feedback is provided to reporters	Yes ☒ No ☐	2011	moh
5.10.16S	The ADR database is computerized	Yes ☒ No ☐	2011	moh
5.10.17S	Medication errors (MEs) are reported	Yes ☒ No ☐	2011	moh
5.10.18S	How many MEs are there in the ADRs database?			moh
5.10.19S	There is a risk management plan presented as part of product dossier submitted for Marketing Authorization?	Yes ☒ No ☐	2011	moh
5.10.20S	In the past two years, who has reported ADRs?		2011	moh
5.10.20.01S	Doctors	☒ Yes		

5.10.20.02S	Nurses	☐ Yes		
5.10.20.03S	Pharmacists	☒ Yes		
5.10.20.04S	Consumers	☐ Yes		
5.10.20.05S	Pharmaceutical Companies	☐ Yes		
5.10.20.06S	Others, please specify whom			
5.10.21S	Was there any regulatory decision based on local pharmacovigilance data in the last 2 years?	Yes ☒ No ☐	2011	moh
5.10.22S	Are there training courses in pharmacovigilance?	Yes ☒ No ☐	2011	moh
5.10.22.01S	If yes, how many people have been trained in the last two years?	1	2011	moh
5.10.23S	Comments and References			

Section 6 Medicines Financing

6.00 Respondent Information Section 5

6.00.01	Name of person responsible for filling out this section of the instrument	Pharmacist Jamila Z. Lafta
6.00.02	Phone number	+964 790 194 5692
6.00.03	Email address	pharmacydepmoh@yahoo.com
6.00.04	Other respondents for this sections	

6.01 Medicines Coverage and Exemptions

Core Questions (click here for help)

			Year	Source
6.01.01	Do the followings receive medicines free of charge:		2007	WHO level I
6.01.01.01	Patients who cannot afford them	Yes ☒ No ☐		
6.01.01.02	Children under 5	Yes ☒ No ☐		
6.01.01.03	Pregnant women	Yes ☒ No ☐		
6.01.01.04	Elderly persons	Yes ☒ No ☐		
6.01.01.05	Please describe/explain your yes answers for questions above	all medicins are provided free of charge to all Iraqies as per the iraqi constitution		
6.01.02	Is there a public health system or social health insurance scheme or public programme providing medicines free of charge for :			iraqi constitution
6.01.02.01	All medicines included in the EML	Yes ☒ No ☐		
6.01.02.02	Any non-communicable diseases	Yes ☒ No ☐		
6.01.02.03	Malaria medicines	Yes ☒ No ☐		
6.01.02.04	Tuberculosis medicines	Yes ☒ No ☐		

6.01.02.05	Sexually transmitted diseases medicines	Yes ☒ No ☐	
6.01.02.06	HIV/AIDS medicines	Yes ☒ No ☐	
6.01.02.07	Expanded Program on Immunization (EPI) vaccines	Yes ☒ No ☐	
6.01.02.08	If others, please specify	any health problem	
6.01.02.09	Please describe/explain your yes answers for questions above	all medicins are provided free of charge to all iraqies as per the iraqi constitution	
6.01.03	Does a national health insurance, social insurance or other sickness fund provide at least partial medicines coverage?	Yes ☐ No ☒	moh
6.01.03.01	Does it provide coverage for medicines that are on the EML for inpatients	Yes ☐ No ☒	
6.01.03.02	Does it provide coverage for medicines that are on the EML for outpatients	Yes ☐ No ☒	
6.01.03.03	Please describe the medicines benefit of public/social insurance schemes		
6.01.04	Do private health insurance schemes provide any medicines coverage?	Yes ☐ No ☒	moh
6.01.04.01	If yes, is it required to provide coverage for medicines that are on the EML?	Yes ☐ No ☐	
6.01.05	Comments and References	In Iraq, there is no private health insurance. All Iraqis receive health care and medicines either free of charge or for a very minimal (symbolic) fee.	

6.02 Patients Fees and Copayments

Core Questions (click here for help)

	Year	Source

6.02.01	In your health system, at the point of delivery, are there any co-payment/fee requirements for consultations	Yes ☒ No ☐	2010	moh
6.02.02	In your health system, at the point of delivery, are there any co-payment/fee requirements for medicines	Yes ☐ No ☒	2010	moh
6.02.03	In practice, (even though this may be contrary to regulations) is revenue from fees or sales of medicines sometimes used to pay the salaries or supplement the income of public health personnel in the same facility?	Yes ☐ No ☒	2007	WHO level I
6.02.03.01	Please describe the patient fees and copayments system	minimal or symbolic fees		
6.02.04	Comments and References			
6.03 Pricing Regulation for the Private Sector **Core Questions (click here for help)**				
			Year	Source
6.03.01	Are there legal or regulatory provisions affecting pricing of medicines	Yes ☐ No ☒	2010	MOH
6.03.01.01	If yes, are the provisions aimed at Manufacturers	Yes ☐ No ☐		
6.03.01.02	If yes, are the provisions aimed at Wholesalers	Yes ☐ No ☐		
6.03.01.03	If yes, are the provisions aimed at Retailers	Yes ☐ No ☐		
6.03.01.04	Please explain the positive answers above: (explain scope of provisions i.e generics vs. originator or subsets of medicines, EML etc.)			
6.03.02	Government runs an active national medicines price monitoring system	Yes ☐ No ☒	2010	MOH

	for retail prices			
6.03.03	Regulations exists mandating that retail medicine price information should be publicly accessible	Yes ☐ No ☒	2010	MOH
6.03.03.01	-if yes, please explain how the information is made publically available			
6.03.04	Comments and References			

6.04 Prices, Availability and Affordability

Core Questions (click here for help)

			Year	Source
6.04.01-04	Please state if a medicines price survey using the WHO/HAI methodology has been conducted in the past 5 years in your country. **If yes**, please indicate the year of the survey and use the results to fill in this table ***If no***, but other surveys on medicines prices and availability have been conducted, please do not use them to fill in this section, but rather use the comment box to write some of the results and attach the report to the questionnaire	Yes ☐ No ☒ Unknown ☐		

	Basket Of key medicines			Public procurement	Public patient	Private patient		
	Availability (one or both of)	**Mean (%)**	**Orig**		6.04.01.01	6.04.01.03		
			LPG		6.04.01.02	6.04.01.04		
		Median (%)	**Orig**		6.04.02.01	6.04.02.03		

			LPG		6.04.02.02	6.04.02.04	
	Price	**Median Price Ratio**	**Orig**	6.04.03.01	6.04.03.03	6.04.03.05	
			LPG	6.04.03.02	6.04.03.04	6.04.03.06	
	Affordability Days' wages of the lowest paid govt worker for standard treatment with co-trimoxazole for a child respiratory infection	**Number of days' wages**	**Orig**		6.04.04.01	6.04.04.03	
			LPG		6.04.04.02	6.04.04.04	
6.04.05	Comments and References						

6.05 Price Components and Affordability

Core Questions (click here for help)

			Year	Source
6.05.01	Please state if a survey of medicines price components has been conducted in the past 5 years in your country	Yes ☐ No ☒ Unknown ☐		MOH
6.05.02	Median cumulative percentage mark-up between Manufacturer Selling Price (MSP)/ Cost Insurance and Freight (CIF) price and final medicine price for a basket of key medicines in the public sector (Median % contribution)			
6.05.03	Median cumulative percentage mark-up between MSP/CIF price and final medicine price for a basket of key medicines in the private sector (Median % contribution)			

6.05.04	Comment and References		
Supplementary questions (click here for help)			
6.05.05S	Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the public sector (Median % contribution)		
6.05.06S	Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the private sector (Median % contribution)		
6.05.07S	Median manufacturer selling price (CIF) as percent of final medicine price for a basket of key medicines (%)		
6.05.08S	Median wholesaler selling price as percent of final medicine price for a basket of key medicines (%)		
6.05.09S	Median pharmacist mark-up or dispensing fee as percent of retail price for a basket of key medicines (%)		
6.05.10S	Median percentage contribution of the wholesale mark-up to final medicine price for a basket of key medicines (in the public and private sectors) (%)		
6.05.11S	Median percentage contribution of the retail mark-up to final medicine price for a basket of key medicines (in the public and private sectors) (%)		
6.05.12S	Comment and References		
6.06 Duties and Taxes on Pharmaceuticals (Market) **Core Questions (click here for help)**			
		Year	Source

6.06.01	There are duties on imported active pharmaceutical ingredients (APIs)	Yes ☐ No ☒	2011	KIMADIA
6.06.02	There are duties on imported finished products	Yes ☐ No ☒	2011	KIMADIA
6.06.03	VAT (value-added tax) or any other tax is levied on finished pharmaceuticals products	Yes ☐ No ☒	2011	KIMADIA
6.06.04	There are provisions for tax exceptions or waivers for pharmaceuticals and health products	Yes ☒ No ☐	2011	KIMADIA
6.06.05	Please specify categories of pharmaceuticals on which the taxes are applied and describe the exemptions and waivers that exist	Medicines are not subjected to taxes		
6.06.06	Comments and References			

Supplementary questions (click here for help)

			Year	Source
6.06.07S	Duty on imported active pharmaceutical ingredients, APIs (%)			
6.06.08S	Duty on imported finished products (%)			
6.06.09S	VAT on pharmaceutical products (%)			
6.06.10S	Comments and References			

Section 7 Pharmaceutical procurement and distribution

7.00 Respondent Information Section 6

7.00.01	Name of person responsible for filling out this section of the instrument	Qais J. Talib
7.00.02	Phone number	+964 790 111 6457
7.00.03	Email address	dg@kim-moh.net
7.00.04	Other respondents for filling out this section	

7.01 Public Sector Procurement

Core Questions (click here for help)

			Date	Source
7.01.01	Public sector procurement is:		2011	KIMADIA
7.01.01.01	Decentralized	☐ Yes		
7.01.01.02	Centralized and decentralized	☒ Yes		
7.01.01.03	Please describe			
7.01.02	If public sector procurement is wholly or partially centralized, it is under the responsibility of a procurement agency which is:		2011	KIMADIA
7.01.02.01	Part of MoH	Yes ☒ No ☐		
7.01.02.02	Semi-Autonomous	Yes ☒ No ☐		
7.01.02.03	Autonomous	Yes ☐ No ☒		

7.01.02.04	A government procurement agency which procures all public goods	Yes ☐ No ☒		
7.01.03	Public sector requests for tender documents are publicly available	Yes ☒ No ☐	2011	KIMADIA
7.01.04	Public sector tender awards are publicly available	Yes ☒ No ☐	2011	KIMADIA
7.01.05	Procurement is based on prequalification of suppliers	Yes ☐ No ☒	2011	KIMADIA
7.01.05.01	If yes, please describe how it works	In the public sector it depends on buying a pre-registered & pre-tested medicines in MOH in all cases		
7.01.06	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
7.01.07S	Is there a written public sector procurement policy?. If yes, please write the year of approval in the "year" field	Yes ☒ No ☐		
7.01.08S	Are there legal provisions giving priority in public procurement to goods produced by local manufacturers?	Yes ☒ No ☐	2005	IRAQI CONSTITUTION
7.01.09S	The key functions of the procurement unit and those of the tender committee are clearly separated	Yes ☒ No ☐	2007	WHO level I
7.01.10S	A process exists to ensure the quality of products procured	Yes ☒ No ☐	1981	LAW OF PUBLIC HEALTH NO 89
7.01.10.01S	If yes, the quality assurance process includes pre-qualification of products and suppliers	Yes ☒ No ☐		
7.01.10.02S	If yes, explicit criteria and procedures exist for pre-	Yes ☒ No ☐		

	qualification of suppliers			
7.01.10.03S	If yes, a list of pre-qualified suppliers and products is publicly available	Yes ☒ No ☐		
7.01.11S	List of samples tested during the procurement process and results of quality testing are available	Yes ☒ No ☐	2010	KIMADIA
7.01.12S	Which of the following tender methods are used in public sector procurement:		2010	KIMADIA
7.01.12.01S	National competitive tenders	Yes ☒ No ☐		
7.01.12.02S	International competitive tenders	Yes ☒ No ☐		
7.01.12.03S	Direct purchasing	Yes ☒ No ☐		
7.01.13S	Comments and References			

7.02 Public Sector Distribution

Core Questions (click here for help)

			Year	Source
7.02.01	The government supply system department has a Central Medical Store at National Level	Yes ☒ No ☐	2010	KIMADIA
7.02.02	Number of public warehouses in the secondary tier of public distribution (State/Regional/Provincial)	6	2010	KIMADIA
7.02.03	There are national guidelines on Good Distribution Practices (GDP)	Yes ☐ No ☒	2010	KIMADIA
7.02.04	There is a licensing authority that issues GDP licenses	Yes ☐ No ☒		KIMADIA
7.02.04.01	If a licensing authority exists, does	Yes ☐ No ☐		

	it accredit public distribution facilities?			
7.02.05	List of GDP certified warehouses in the public sector exists	Yes ☐ No ☒		KIMADIA
7.02.06	List of GDP certified distributors in the public sector exists	Yes ☐ No ☐		KIMADIA
7.02.07	Comments and References			

Supplementary questions (click here for help)

			Year	Source
7.02.08S	Which of the following processes is in place at the Central Medical Store:			
7.02.08.01S	Forecasting of order quantities	Yes ☒ No ☐		
7.02.08.02S	Requisition/Stock orders	Yes ☒ No ☐		
7.02.08.03S	Preparation of picking/packing slips	Yes ☒ No ☐		
7.02.08.04S	Reports of stock on hand	Yes ☒ No ☐		
7.02.08.05S	Reports of outstanding order lines	Yes ☒ No ☐		
7.02.08.06S	Expiry dates management	Yes ☒ No ☐		
7.02.08.07S	Batch tracking	Yes ☒ No ☐		
7.02.08.08S	Reports of products out of stock	Yes ☒ No ☐		
7.02.09S	Percentage % availability of key medicines at the Central Medical Store	88	2010	KIMADIA
7.02.10S	Average stock-out duration for a basket of medicines at the Central Medical Store, in days			
7.02.11S	Routine Procedure exists to track the expiry dates of medicines at the Central Medical Store	Yes ☒ No ☐	2010	KIMADIA

7.02.12S	The Public Central Medical Store is GDP certified by a licensing authority	Yes ☐ No ☒	2010	KIMADIA
7.02.13S	The Public Central Medical Store is ISO certified	Yes ☐ No ☒	2010	KIMADIA
7.02.14S	The second tier public warehouses are GDP certified by a licensing authority	Yes ☐ No ☒	2010	KIMADIA
7.02.15S	The second tier public warehouses are ISO certified	Yes ☐ No ☒	2010	KIMADIA
7.02.16S	Comments and References			

7.03 Private Sector Distribution

Core Questions (click here for help)

			Year	Source
7.03.01	Legal provisions exist for licensing wholesalers in the private sector	Yes ☒ No ☐	1970	Law of pharmaceutical practice
7.03.02	Legal provisions exist for licensing distributors in the private sector	Yes ☐ No ☒	2010	moh
7.03.03	List of GDP certified wholesalers in the private sector exists	Yes ☐ No ☒	2010	moh
7.03.04	List of GDP certified distributors in the private sector exists	Yes ☐ No ☒	2010	moh
7.03.05	Comments and References			

Section 8 Selection and rational use

8.00 Respondent Information Section 7

8.00.01	Name of person responsible for filling out this section of the instrument	Pharmacist Jamila Z. Lafta
8.00.02	Phone number	+964 790 194 5692
8.00.03	Email address	pharmacydepmoh@yahoo.com
8.00.04	Other respondents for filling out this section	

8.01 National Structures

Core Questions (click here for help)

			Year	Source
8.01.01	National essential medicines list (EML) exists. If yes, please write year of last update of EML in the "year" field	Yes ☒ No ☐	2011	MOH
8.01.01.01	If yes, number of medicines on the EML (no. of INN)	1,259		
8.01.01.02	If yes, there is a written process for selecting medicines on the EML	Yes ☒ No ☐		
8.01.01.03	If yes, the EML is publicly available	Yes ☒ No ☐		
8.01.01.04	If yes, is there any mechanism in place to align the EML with the Standard Treatment Guidelines (STG)	Yes ☐ No ☒		
8.01.02	National Standard Treatment Guidelines (STGs) for most common illnesses are produced/endorsed by the MoH. If yes, please insert year of last update of STGs in the "year" field	Yes ☐ No ☒		MOH

8.01.03	STGs specific to Primary care exist. Please use the "year" field to write the year of last update of primary care guidelines	Yes ☐ No ☒		MOH
8.01.04	STGs specific to Secondary care (hospitals) exists. Please use the "year" field to write the year of last update of secondary care STGs.	Yes ☐ No ☒		MOH
8.01.05	STGs specific to Paediatric conditions exist. Please use the "year" field to write the year of last update of paediatric condition STGs	Yes ☐ No ☒	2007	MOH
8.01.06	% of public health facilities with copy of EML (mean)- Survey data	100	2010	MOH
8.01.07	% of public health facilities with copy of STGs (mean)- Survey data			
8.01.08	A public or independently funded national medicines information centre provides information on medicines to prescribers, dispensers and consumers	Yes ☐ No ☒	2007	MOH
8.01.09	Public education campaigns on rational medicine use topics have been conducted in the previous two years	Yes ☐ No ☒	2011	MOH
8.01.10	A survey on rational medicine use has been conducted in the previous two years	Yes ☐ No ☒	2011	MOH
8.01.11	A national programme or committee (involving government, civil society, and professional bodies) exists to monitor and promote rational use of medicines	Yes ☒ No ☐	2010	MOH
8.01.12	A written National strategy exists to contain antimicrobial resistance. If yes, please write year of last update of the strategy in the "year"	Yes ☒ No ☐	2010	MOH

	field			
8.01.13	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
8.01.14S	The Essential Medicines List (EML) includes formulations specific for children	Yes ☒ No ☐	2011	MOH
8.01.15S	There are explicitly documented criteria for the selection of medicines in the EML	Yes ☒ No ☐	2008	MOH
8.01.16S	There is a formal committee or other equivalent structure for the selection of products on the National EML	Yes ☒ No ☐	2007	MOH
8.01.16.01S	If yes, conflict of interest declarations are required from members of national EML committee	Yes ☐ No ☒		
8.01.17S	National medicines formulary exists	Yes ☒ No ☐	2010	MOH
8.01.18S	Is there a funded national inter-sectoral task force to coordinate the promotion of appropriate use of antimicrobials and prevention of spread of infection?	Yes ☐ No ☒	2007	MOH
8.01.19S	A national reference laboratory/or any other institution has responsibility for coordinating epidemiological surveillance of antimicrobial resistance	Yes ☒ No ☐	2011	MOH
8.01.20S	Comments and References	8.01.11(SPECIFIC FOR ANTIBIOTIC) 8.01.12(menistrial instruction & regulations) 8.01.15S(criteria are included in NMP)		

8.02 Prescribing

Core Questions (click here for help)				
			Year	Source
8.02.01	Legal provisions exist to govern the licensing and prescribing practices of prescriber	Yes ☒ No ☐	2007	MOH
8.02.02	Legal provisions exist to restrict dispensing by prescribers	Yes ☒ No ☐	2010	MOH(meni sterial instruction)
8.02.03	Do prescribers in the private sector dispense medicines?	Yes ☐ No ☒	2007	MOH
8.02.04	Regulations require hospitals to organize/develop Drug and Therapeutics Committees (DTCs)	Yes ☒ No ☐	2007	MOH
8.02.05	Do more than half of referral hospitals have a DTC?	Yes ☒ No ☐ Unknown ☐	2007	MOH
8.02.06	Do more than half of general hospitals have a DTC?	Yes ☒ No ☐ Unknown ☐	2007	MOH
8.02.07	Do more than half of regions/provinces have a DTC?	Yes ☒ No ☐ Unknown ☐	2010	MOH
8.02.08	The core medical training curriculum includes components on:			
8.02.08.01	Concept of EML	Yes ☒ No ☐		
8.02.08.02	Use of STGs	Yes ☐ No ☒		
8.02.08.03	Pharmacovigilance	Yes ☒ No ☐		
8.02.08.04	Problem based pharmacotherapy	Yes ☒ No ☐		
8.02.09	Mandatory continuing education that includes pharmaceutical issues is required for doctors (see physician)	Yes ☒ No ☐	2010	moh
8.02.10	Mandatory continuing education that includes pharmaceutical issues is required for nurses	Yes ☒ No ☐	2010	MOH

8.02.11	Mandatory continuing education that includes pharmaceutical issues is required for paramedical staff	Yes ☒ No ☐	2010	MOH
8.02.12	Prescribing by INN name is obligatory in:			
8.02.12.01	Public sector	Yes ☒ No ☐		
8.02.12.02	Private sector	Yes ☐ No ☒		
8.02.13	Average number of medicines prescribed per patient contact in public health facilities (mean)	3	2010	MOH
8.02.14	% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)		2010	MOH
8.02.15	% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)	100	2010	MOH
8.02.16	% of patients in outpatient public health care facilities receiving antibiotics (mean)	71.7	1992	WHO rational use database
8.02.17	% of patients in outpatient public health care facilities receiving injections (mean)			
8.02.18	% of prescribed drugs dispensed to patients (mean)	95	2010	MOH
8.02.19	% of medicines adequately labeled in public health facilities (mean)	100	2010	MOH
8.02.20	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
8.02.21S	A professional association code of conduct exists governing professional behaviour of doctors	Yes ☐ No ☒	2010	MOH

8.02.22S	A professional association code of conduct exists governing professional behaviour of nurses	Yes ☐ No ☒		
8.02.23S	Diarrhoea in children treated with Oral Rehydration Solution (ORS) (%)			
8.02.24S	Comments and References			

8.03 Dispensing

Core Questions (click here for help)

			Year	Source
8.03.01	Legal provisions exist to govern dispensing practices of pharmaceutical personnel	Yes ☐ No ☒	2010	MOH
8.03.02	The basic pharmacist training curriculum includes components on:		2011	MOH
8.03.02.01	Concept of EML	Yes ☒ No ☐		
8.03.02.02	Use of STGs	Yes ☒ No ☐		
8.03.02.03	Drug Information	Yes ☒ No ☐		
8.03.02.04	Clinical pharmacology	Yes ☒ No ☐		
8.03.02.05	Medicines supply management	Yes ☒ No ☐		
8.03.03	Mandatory continuing education that includes rational use of medicines is required for pharmacists	Yes ☒ No ☐	2011	MOH
8.03.04	Generic substitution at the point of dispensing in public sector facilities is allowed	Yes ☒ No ☐	2011	MOH
8.03.05	Generic substitution at the point of dispensing in private sector facilities is allowed	Yes ☐ No ☒	2011	MOH

8.03.06	In practice, (even though this may be contrary to regulations) are antibiotics sometimes sold over-the-counter without any prescription?	Yes ☒ No ☐ Unknown ☐	2007	MOH
8.03.07	In practice, (even though this may be contrary to regulations) are injections sometimes sold over-the-counter without any prescription?	Yes ☒ No ☐ Unknown ☐	2007	MOH
8.03.08	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
8.03.09S	A professional association code of conduct exists governing professional behaviour of pharmacists	Yes ☐ No ☒		MOH
8.03.10S	In practice, (even though this may be contrary to regulations) do the following groups of staff *sometimes* prescribe prescription-only medicines at the primary care level in the public sector?		2007	MOH
8.03.10.01S	Nurses	Yes ☐ No ☒ Unknown ☐		
8.03.10.02S	Pharmacists	Yes ☐ No ☒ Unknown ☐		
8.03.10.03S	Paramedics	Yes ☒ No ☐ Unknown ☐		
8.03.10.04S	Personnel with less than one month training	Yes ☐ No ☒ Unknown ☐		
8.03.11S	Comments and References	8.03.10.03S (in health center that are manage by paramedic in rural areas)		

Section 9 Household data/access

9.00 Respondent Information section 8

9.00.01	Name of person responsible for filling out this section of the instrument	pharmacist Jamila Z. Lafta
9.00.02	Phone number	+964 790 194 5692
9.00.03	Email address	pharmacydepmoh@yaho.com
9.00.04	Other respondents for filling out this section	

9.01 Data from Household Surveys

Core Questions (click here for help)

			Year	Source
9.01.01	What household surveys have been undertaken in the past 5 years to assess access to medicines?	Iraq Family Health Survey	2005	MOH
9.01.02	Adults with acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)			MOH
9.01.03	Adults with acute conditions not taking all medicines because they cannot afford them (%)			MOH
9.01.04	Adults (from poor households) with an acute health condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)			MOH
9.01.05	Adults (from poor households) with an acute condition in two-week recall period who did not take all medicines because they cannot afford them (%)			MOH

9.01.06	Adults with chronic conditions taking all medicines prescribed by an authorized prescriber (%)			MOH
9.01.07	Adults (from poor households) with chronic conditions not taking all medicines because they cannot afford them (%)			MOH
9.01.08	Adults (from poor households) with chronic conditions who usually take all medicines prescribed by an authorized prescriber (%)			MOH
9.01.09	Children (from poor households) with an acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)			MOH
9.01.10	Percentage of people who obtained the medicines prescribed in the 15 days before the interview (%)			MOH
9.01.11	People who obtained prescribed medicines for free in the 15 days before the interview (%)			MOH
9.01.12	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
9.01.13S	Adults with acute conditions not taking all medicines because the medicines were not available (%)			MOH
9.01.14S	Adults with chronic conditions not taking all medicines because they cannot afford them (%)			MOH
9.01.15S	Adults with chronic conditions not taking all medicines because the medicines were not available (%)			MOH
9.01.16S	Children with acute conditions taking all medicines prescribed by			MOH

	an authorized prescriber (%)			
9.01.17S	Children with acute conditions not taking all medicines because they cannot afford them (%)			MOH
9.01.18S	Children with acute conditions not taking all medicines because the medicines were not available (%)			MOH
9.01.19S	Children (from poor households) with acute conditions not taking all medicines because they cannot afford them (%)			MOH
9.01.20S	Comments and References			

Key Documents to be attached

Document	Exact title	Author	Publisher	Year	File name
National Medicines Policy (NMP)					
NMP implementation plan					
National Medicines Act					
National pharmaceutical human resources report or strategic plan					
Latest report on the national pharmaceutical market (any source)					
National Pharmacovigilance Centre report (including Adverse Drug Reaction, ADR, analysis report in the last two years)					
National pharmaceutical legislation for regulation					
Annual report of quality control laboratories					
Annual report of national regulatory authority					
Legal provisions on medicines price regulations					
Medicines procurement policy					
National Essential Medicines List (EML)					
National Standard Treatment Guidelines (STGs)					
National Strategy for anti-microbial resistance					

Any other medicines pricing/availability surveys, household surveys, and rational use surveys than the ones used to prefill in the instrument.					