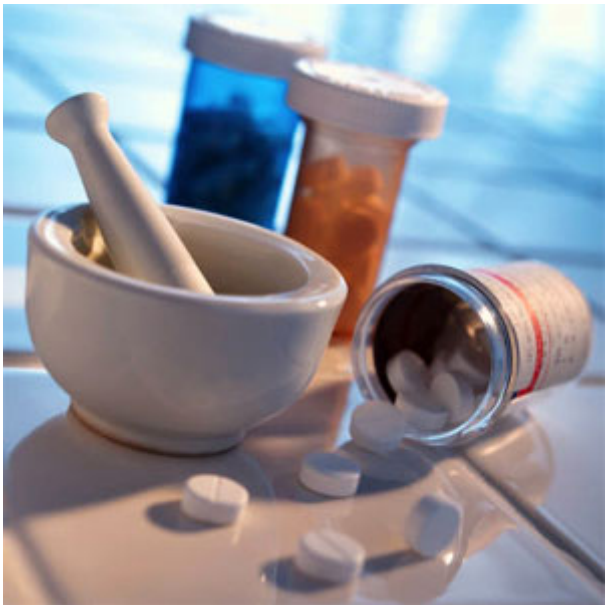
EGYPT

PHARMACEUTICAL COUNTRY PROFILE



Egypt Pharmaceutical Country Profile

Published by the Ministry of Health Egypt in collaboration with the World Health Organization

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Foreword

The 2011 Pharmaceutical Country Profile for Egypt 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 Egypt. 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 Egypt, I wish to express my appreciation to Dr.Mahmoud Diaa, PharmD from the MOH Central Administration for Pharmaceutical Affairs for his contribution 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 Egypt pharmaceutical sector will find this profile a useful tool to aid their activities.

Aiman Saad El-Khatib
Assistant Minister of Health and Population for Pharmaceutical Affairs

Date: 27-11-2011

Official Authorization
for use of data included in the
Country Pharmaceutical Sector Profile Questionnaire

On behalf of the Ministry of Health of Egypt I confirm that the data included into this Country Pharmaceutical Sector Profile Questionnaire is correct, to the best of my knowledge.

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Function in the Ministry of Health .....

Date: 27/11/2011

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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 Egypt. 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 Egypt was Mahmoud Elmahdawy, Pharm D.

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 CAPA, Hospital Pharmacy Administration. 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 Egypt.

1.1 Demographics and Socioeconomic Indicators

The total population of Egypt in 2009 was 82,999,000 with an annual population growth rate of 1.9%[1]. The annual GDP growth rate is 4.6 %[3]. The GDP per capita was US$ 2,270 (at the current exchange rate[i])[3].

32% of the population is under 15 years of age, and 7% of the population is over 60 years of age. The urban population currently stands at 43% or the total population. The fertility rate in Egypt is 2.8 births per woman.[1] 2 % of the population is living with less than $1.25/day (international PPP). The income share held by the lowest 20% of the population is 9% (as a % of national income).[3] The adult literacy rate for the population over 15 years is 66 %.[1]

1.2 Mortality and Causes of Death

The life expectancy at birth is 69 and 73 years for men and women respectively. The infant mortality rate (i.e. children under 1 year) is 18/1,000 live births. For children under the age of 5, the mortality rate is 21/1,000 live births. The maternal mortality rate is 82/100,000 live births[1].

The top 10 diseases causing mortality in Egypt are (Ministry of Health Egypt, 2011, data from 2010)

	Disease
1	Essential primary Hypertension
2	Intracerebral Hemorrhage
3	Fibrosis and cirrhosis of liver
4	Hepatic Failure
5	Atherosclerosis
6	Elevated Blood Glucose level

[i] The exchange rate for calculation for EGP is 1 USD = 5.49 EGP (2008 average exchange rate), 1 USD = which is consistent with the timing of the collection of related NHA data. The current exchange rate used is 1 USD = 5.97 EGP (28-06-2011)

7	Arterial Embolisim and thrombosis
8	Acute myocardial infarction
9	Cerebral infarction
10	other

The top 10 diseases causing morbidity in Egypt are (Ministry of Health Egypt, 2011, data from 2010)

	Disease
1	Infectious Gastroenteritis
2	Spontaneous Labor
3	Caesarean section
4	Acute appendicitis
5	Iron deficiency anemia
6	Respiratory Distress Syndrome (RDS)
7	Broncho pneumonia
8	Acute tonsillitis
9	Forearm Fracture
10	Non specific renal colic

Section 2 - Health Services

This section provides information regarding health expenditures and human resources for health in Egypt. 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 Egypt, the total annual expenditure on health (THE) in 2009 was 61,400 million EGP (10,962 million US$)[4]. The total annual health expenditure was 5.8 % of the GDP. The total annual expenditure on health per capita was 740 EGP (US$ 132)[5].

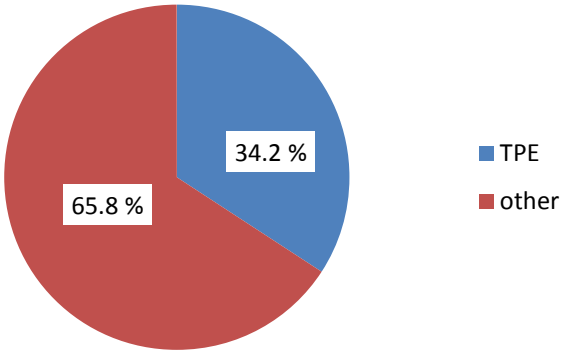
The general government health expenditure (GGHE) in 2009, as reflected in the national health accounts (NHA) was 15,200 million EGP (US$ 2,713 million). That is 24.76 % of the total expenditure on health, with a total annual per capita public expenditure on health of 183.13 EGP (US$ 32.69). The government annual expenditure on health represents 4.3 % of the total government budget. Private health expenditure covers the remaining 95.7 % of the total health expenditure. [4]

Of the total population, 51 % is covered by a public health service, public health insurance or social insurance, or other sickness funds. Data of the % of total population covered by private health insurance is not available.

Total pharmaceutical expenditure (TPE) in Egypt in 2009 was 21,000 million EGP (US$ 3,559 million), which is a per capita pharmaceutical expenditure of 253 EGP (US$ 42.89). The total pharmaceutical expenditure accounts for 1.89 % of the GDP and makes up 34.20 % of the total health expenditure Figure 1. Public expenditure on pharmaceuticals represents 23.31 % of the total

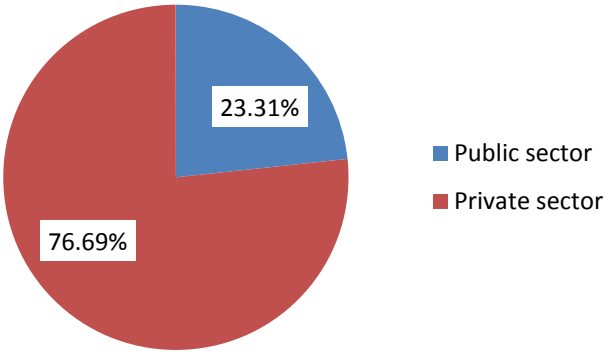
expenditure on pharmaceuticals (Figure 2), this converts into a per capita public expenditure on pharmaceuticals of 31EGP (US$ 5.6)[6].

FIGURE 1: Share of Total Pharmaceutical Expenditure as percentage of the Total Health Expenditure 2009. The THE in 2009 was 61,400 million EGP (10,962 million US$)



Source: NHA 2009

FIGURE 2: Share of Total Pharmaceutical Expenditure by sector 2008



NHA 2007-2008

Total private expenditure on pharmaceuticals is 8,445.71 million EGP (US$ 1,431.45). [7] Private out-of-pocket expenditure as % of private health

expenditure is 95.14 %. Premiums for private prepaid health plans are 0.22 % of total private health expenditure.[7]

2.2 Health Personnel and Infrastructure

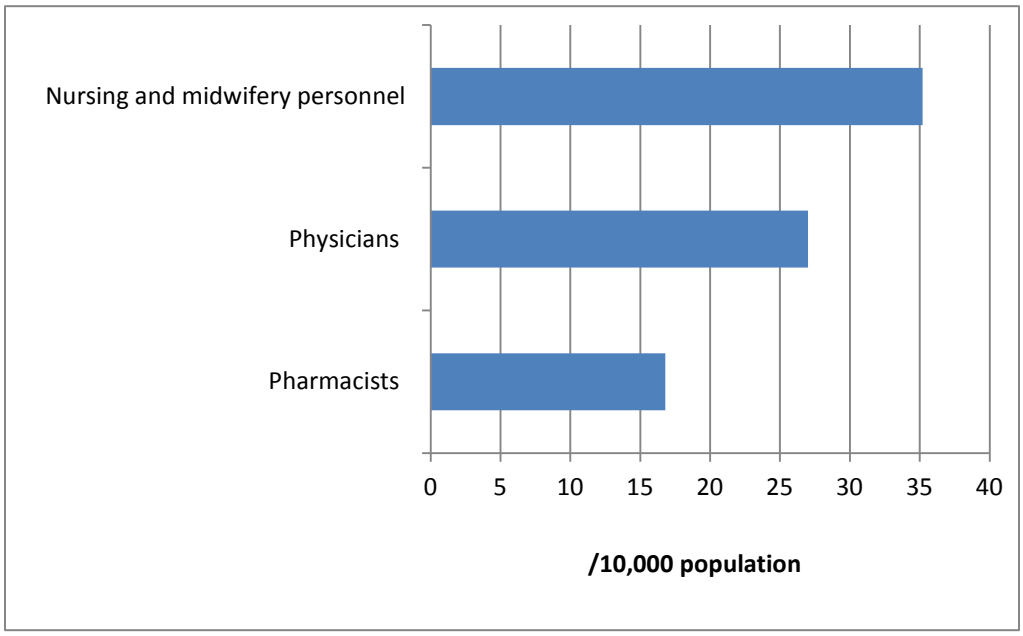
The health workforce is described in the table below and in Figure 3. There are 139,479 (16.8 /10,000) licensed pharmacists, of which 15,457 (1.86 /10,000) work in the public sector. (The number of pharmacists may be slightly lower than the actual number because a small number work in miscellaneous public jobs and are included in any total database.)

There are 232,203 (27 /10,000) physicians and 280.561 (35.2 /10,000) nursing and midwifery personnel in Egypt. The ratio of doctors to pharmacists is 1.6 and the ratio of doctors to nurses and midwifery personnel is 0.8.

Table 1: Human resources for health in Egypt (2011)

Human Resource	
Licensed pharmacists (all sectors)	139,479 (16.8 /10,000)[8]
Pharmacists in the public sector	15,457 (1.9 /10,000)[11]
Pharmaceutical technicians and assistants	unknown
Physicians (all sectors)	223,203 (27 /10,000)[9]
Nursing and midwifery personnel (all sectors)	280,561 (35.2 /10,000)1

Figure 3: The density of the Health Workforce 2011 in Egypt (all sectors)



Source: Egyptian Pharmacists Syndicate; CAPA; Egyptian Medical Syndicate; WHS 2011

In Egypt, there is a strategic plan for pharmaceutical human resource development in place (objectives of development that will be made into a plan)[10]. The health workforce is described in the table below. There are 1,969 hospitals and 15.49 hospital beds per 10,000 pop in Egypt. There are 5,034 primary health care units and centres and 59,798 licensed pharmacies.

Table 2: Health centre and hospital statistics

Infrastructure	
Hospitals	1969[11]
Hospital beds	128,573 (15.49/10,000)[11]
Primary health care units and centres	5034[11]
Licensed pharmacies (only community pharmacies without hospital pharmacies)	59,79810

The annual starting salary for a newly registered pharmacist in the public sector is 13,800 EGP. Accreditation requirements for pharmacy schools are in place. The pharmacy Curriculum is regularly reviewed.

Section 3 - Policy Issues

This section addresses the main characteristics of the pharmaceutical policy in Egypt. 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 Egypt, a National Health Policy (NHP) exists.[12] It was updated in 2005. An associated National Health Policy implementation plan written in 2006 also exists.[12]

An official National Medicines Policy document exists in Egypt[13]. It was updated in 2005. A NMP implementation plan does not exist. Policies addressing pharmaceuticals exist, as detailed in Table 2[14]. Pharmaceutical policy implementation is regularly monitored/assessed by the Egyptian Drug Authority (EDA).[15]

Table 3: The NMP/group of policies cover:[13 14]

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	No
Monitoring and evaluation	Yes
Traditional Medicine	No

A policy relating to clinical laboratories does not exist. An associated National clinical laboratory policy implementation plan does not exist. Access to essential medicines/technologies as part of the fulfillment of the right to health, is recognized in the constitution or national legislation[14]. There are official written guidelines on medicines donations[13].

There is no national good governance policy in Egypt. *(Comment: There is limited non-governmental good governance in Egypt to our knowledge.)*

A policy is in place to manage and sanction conflict of interest issues in pharmaceutical affairs. There is an 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 Egypt exists[16]. Each Ministry in the government has an office for Citizen's Services, where any citizen can report any wrongdoing occurred with him in that ministry. Then this complaint is processed for further investigation.

Section 4 – Medicines Trade and Production

4.1 Intellectual Property Laws and Medicines

Egypt is a member of the World Trade Organization[17]. Legal provisions granting patents to manufacturers exist. These cover pharmaceuticals.

Intellectual Property Rights are managed and enforced by the Egyptian Patent Office (ASRT) (URL: www.egypo.gov.eg)[18].

National Legislation has been modified to implement the TRIPS Agreement and contains TRIPS-specific flexibilities and safeguards[19], presented in Table 4. Egypt 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	Yes
Bolar exceptions[ii]	Yes
Parallel importing provisions	Yes

[ii] 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 on line at: http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf]

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

The country is engaged in capacity-strengthening initiatives to manage and apply Intellectual Property Rights in order to contribute to innovation and promote public health. There are three projects for innovation with the World Intellectual Property Organization (WIPO): TISC, TTO, IP Academy.

4.2 Manufacturing

There are 119 licensed pharmaceutical manufacturers in Egypt. Manufacturing capabilities are presented in Table 5 below.

Table 5: Egypt manufacturing capabilities[20]

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

Section 5 – Medicines Regulation

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

5.1 Regulatory Framework

In Egypt, there are legal provisions establishing the powers and responsibilities of the Medicines Regulatory Authority (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 address is www.eda.mohp.gov.eg. The Egyptian Drug Authority (EDA) is the pharmaceutical regulatory body of the Egyptian Ministry of Health. EDA has three sub-organizations: CAPA, NODCAR, NORCB.10

Table 6: Functions of the national MRA[15]

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	No
Pharmacovigilance	Yes

As of 2011, there were 820 permanent staff working for the MRA (CAPA). The MRA receives external technical assistance to support its activities (technical committees formed of external professors).[15] The MRA is not involved in harmonization/collaboration initiatives. An assessment of the medicines regulatory system has been conducted in the last five year. # Funding for the MRA is provided through the regular government budget as well as through fees

from services provided. The Regulatory Authority retains 50% of 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[15].

5.2 Marketing Authorization (Registration)

In Egypt, legal provisions require marketing authorization (registration) for all pharmaceutical products on the market, however exceptions/waivers for registration do exist. Mutual recognitions mechanisms are in place: under certain requirements: for prescriptions only, reports from physicians, through an Egyptian drug distribution company[15]. Explicit and publicly available criteria exist for assessing applications for marketing authorization of pharmaceutical products[15]. In 2011, there were 8973 pharmaceutical products registered in Egypt. 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 10 years. The updated list can be accessed through http://www.eda.mohealth.gov.eg/Services/Drug_Hum.aspx?Main=Services&Serviceid=2&Submain=serv7. Medicines are 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[15].

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. Furthermore, legal provisions requiring the establishment of an expert committee involved in the Marketing Authorization process are in place.[28] Possession of a Certificate for Pharmaceutical Products (that accords with the WHO Certification scheme) is not 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 fee for generic pharmaceutical products is US$ 1,675.[21]

The time limit imposed for the assessment of all Marketing Authorization applications is 12 months.

5.3 Regulatory Inspection

In Egypt, legal provisions exist allowing for appointment of government pharmaceutical inspectors[22]. 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.[13] Where inspections are legal requirements, these are the same for public and private facilities. Exception: 1) The expired drugs in the public facilities are not present however in private facilities they are present in isolated places until they are returned to suppliers. 2) Inspection on inventory present in public facilities. [23] Inspections are carried out on a number of entities, outlined in Table 7.

Table 7: Local entities inspected for GMP compliance[13]

Entity	Inspection	Frequency
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 do not exist to allow for inspection of imported pharmaceutical products at authorized ports of entry[24].

5.5 Licensing

In Egypt, legal provisions exist requiring manufacturers to be licensed[13]. Legal provisions exist requiring manufacturers (both domestic and international) to comply with Good Manufacturing Practices (GMP). Good Manufacturing Practices are published by the government[25].

Legal provisions exist requiring importers/wholesalers/distributers to be licensed.[23] Legal provisions exist requiring wholesalers and distributors to comply with Good Distributing Practices.[23] [26]

Table 8: Legal provisions pertaining to licensing

Entity requiring licensing	
Importers	Yes
Wholesalers	Yes
Distributors	Yes

Good Distribution Practices are published by the government[23].

Legal provisions requiring pharmacists to be registered exist. Legal provisions exist requiring private and public pharmacies to be licensed[27]. National Good Pharmacy Practice Guidelines are published by the government[15]. By law, a list of all licensed pharmaceutical facilities is required to be published.

5.6 Market Control and Quality Control

In Egypt, legal provisions exist for controlling the pharmaceutical market[28]. A laboratory exist in Egypt for Quality Control testing[15].

The laboratory is a functional part of the MRA.

The regulatory authority contracts services elsewhere (The National Organization for Research & Control of Biologicals)

Existing national laboratory facilities have been accepted for collaboration with the WHO pre-qualification Programme – National Organization for Drug Control and Research (NODCAR)[29]. Medicines are tested for a number of reasons, summarised in Table 9.

Table 9: Reason for medicines testing[28]

Medicines tested:	
For quality monitoring in the public sector[iii]	Yes
For quality monitoring in the private sector[iv]	Yes
When there are complaints or problem reports	Yes
For product registration	Yes
For public procurement prequalification	Yes
For public program products prior to acceptance and/or distribution	Yes

Samples are collected by government inspectors for undertaking post-marketing surveillance testing[13].

In the past 2 years, 48,706 samples were taken for quality control testing. Of the samples tested, 277 (or 0.57 %) failed to meet the quality standards.[30] The results are not publicly available.

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

5.7 Medicines Advertising and Promotion

In Egypt, legal provisions exist to control the promotion and/or advertising of prescription medicines. The Medicines Regulatory Authority (Central Administration for Pharmaceutical Affairs) 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 required.[13] [31] Guidelines and Regulations exist for advertising and promotion of non-prescription medicines.[32] There is no national code of conduct concerning advertising and promotion of medicines by marketing authorization holders.

5.8 Clinical Trials

In Egypt, legal provisions requiring authorization for conducting Clinical Trials by the MRA do not exist. 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 not required to be entered into an international/national/regional registry, by law.

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

5.9 Controlled Medicines

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

Table 10: International Conventions to which Egypt is a signatory[33]

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 (Decree 350, EDA, available at: http://www.eda.mohealth.gov.eg/Download/Docs/Decree350.pdf, Accessed: 20-06-11). The annual consumption of Morphine is 0.2195122 mg/capita.[33]

The legal provisions and regulations for the control of narcotic and psychotropic substances, and precursors have not been reviewed by a WHO International Expert or Partner Organization to assess the balance between the prevention of abuse and access for medical need.

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 Egypt[34]

Controlled substance	Annual consumption (mg/capita)
Morphine	0.2195122
Fentanyl	0.02439024
Pethidine	1.09756098
Oxycodone	0.0304878
Hydrocodone	0.06097561
Phenobarbital	73.1707317
Methadone	0.01219512

5.10 Pharmacovigilance

In Egypt, there are legal provisions in the Medicines Act that provide for pharmacovigilance activities as part of the MRA mandate.[35] Legal provisions also exist requiring the Marketing Authorization holder to continuously monitor the safety of their products and report to the MRA.[36] Laws regarding the monitoring of Adverse Drug Reactions (ADR) exist in Egypt. The reporting of ADR by healthcare professionals is optional.[35] A national pharmacovigilance centre linked to the MRA exists.[36]

The Pharmacovigilance centre has 7 full-time staff members (6 pharmacists, 1 administrative assistant).

The centre has not published an analysis report in the previous two years. It publishes an ADR bulletin. An official standardized form for reporting ADRs is used in Egypt. Information pertaining to ADRs is stored in a national ADR database. The ADR database currently comprises 91 ADR reports, of which 91 have been submitted in the past 2 years. These reports are not sent to the WHO collaborating centre in Uppsala[37].

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 Egypt.[36] A clear communication strategy for routine communication and crises communication does not exist.

ADRs are not monitored in any public health program (example TB, HIV, AIDS).

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

- recruiting and training more staff
- finalize the regulatory pharmacovigilance guidelines
- implementation of pharmacovigilance training on large scale for pharmaceutical companies and healthcare professionals
- expanding the awareness campaign to all governorates
- expand speciality of EPVC to include medication errors

Section 6 - Medicines Financing

In this section, information is provided on the medicines financing mechanism in Egypt, 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 Egypt, 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	No
Elderly persons	Yes

Table 13: Medications provided publicly, at no cost[38]

Conditions	Covered
All diseases in the EML	Yes (EML of HIO)
Any non-communicable diseases	No
Malaria	Yes
Tuberculosis	Yes
Sexually transmitted diseases	No
HIV/AIDS	No
Expanded Program on Immunization (EPI) vaccines for children	Yes
Other – bilharzias, hepatitis C	Yes

Medicines are provided free of charge because they are related to endemic diseases in Egypt.[39]

A public health service, public health insurance, social insurance or other sickness fund provides at least partial medicines coverage.
It provides coverage for medicines that are on the Essential Medicines List (EML) for inpatients and outpatient.
There are four classes for HIO beneficiaries:

1) Employees covered through Law 32 of the year 1957 (all employees working in the government sector)
2) Employees covered through Law 79 of 1957 (some public and private sector employees, pensioners, widows)
3) Beneficiaries of the Student Health Insurance Program (SHIP) by law number 99 for year 1992 and covering more than 14 million students, thus increasing the total beneficiary population from 4.895 million in 1992 to 20.67 million in 1995. (Egypt National Health Accounts, 1995).
4) Newly-born children up to age five years, according to ministerial decree number 380 for the year 1997an action that has increased the beneficiary

population by some 9 million, to include approximately 55% of the Egyptian population.

Private health insurance schemes provide medicines coverage.[12]
They are required to provide at least partial coverage for medicines that are on the EML.

6.2 Patients Fees and Co-payments

Co-payments or fee requirements for consultations are not levied at the point of delivery. There are 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[v]

In Egypt, there are legal or regulatory provisions affecting pricing of medicines[40]. These provisions are aimed at the level of manufacturers/wholesalers/retailers. These provisions are applied to all types of medicines in the market (generic, originator EML).

The government runs an active national medicines price monitoring system for retail prices.[41] Regulations exist mandating that retail medicine price information should be publicly accessible[42]. (CAPA Pricing Committee, see http://www.eda.mohealth.gov.eg/Services/CAPAComm.aspx?Main=Services&Serviceid=2&Submain=serv30)

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

6.4 Prices, Availability and Affordability of Key Medicines

In 2004, a WHO/HAI pricing survey was conducted in Egypt[43]. Table 13 provides specific details regarding availability, pricing and affordability in the country.

Availability

Public sector availability of originator medicines was 100 %, while availability of the Lowest priced generic (LPG) medicines was 100 %. Availability in the private sector was 100 % for originator and 100 % for generics.

One explanation for high availability in the public sector is that Egypt has an Essential Drug List which corresponds very well with the core list used in the survey. Although a few essential medicines have been added by use of the supplementary list, average availability remains high. Nevertheless, it has to be remembered that the estimate is based on a one point in time investigation.

Pricing

The Median Price Ratio is used to indicate how prices of medicines in Egypt relate to those on the international market. That is, prices of medicines have been compared to international reference prices[vi] and expressed as a ratio of the national price to the international price. For example, a price ratio of 2 would mean that the price is twice that of the international reference price. Since prices have been collected for a predefined basket of medicines, the Median Price Ratio has been selected to reflect the situation in the country.

Public procurement prices: the Median Price Ratio for generics was 0.95. No originators were found in the governmental sector. As for patient prices, the Median Price Ratio in the public sector was 0.95 for generics, while the private sector had higher prices (1.69 for generics, 2.73 for originators).

[vi] The International reference price is the median of prices offered by international suppliers (both for profit and not profit) as report by MHS International Price Indicator Guide (http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=DMP&language=English). For more information on the methodology WHO/HAI pricing survey, you can download a free copy of the manual at http://apps.who.int/medicinedocs/documents/s14868e/s14868e.pdf.

Affordability

Affordability of medicines is measured in terms of the number of days' of wages necessary to purchase a particular treatment for a specific condition. The wage considered is that paid to the lowest paid government worker in Egypt. Specific data collected for the survey underlying this profile examined the number of days' wages required to purchase treatment with co-trimoxazole (note: data is for amoxicillin, data for co-trimoxazole is not available) for a child respiratory infection; The purchase of generic medication necessitated 0.3 days' wages for public patients and 0.5 for private patients. It is evident, therefore, that generic medicines are less affordable in the private sector than in the public sector.

Table 14: Availability, Pricing and Affordability of medicines in Egypt

		Public procurement	Public patient	Private patient
Availability				
Mean (%)	Originator		100%	100%
	Lowest priced generic (LPG)		100%	100%
Median (%)	Originator			
	Lowest priced generic (LPG)			
Price				
Mean Price Ratio	Originator			2.73
	Lowest priced generic (LPG)	0.95	0.95	1.96
Affordability				
Number of days' wages	Originator			
	Lowest priced generic (LPG)		0.3	0.5

6.5 Price Components and Affordability

In 2004, a survey on medicine price components was conducted in Egypt.[43]

There is not enough data available to complete this section.

6.6 Duties and Taxes on Pharmaceuticals (Market)

Egypt imposes duties on imported active pharmaceutical ingredients (APIs) and duties on imported finished products are imposed. Value-added tax or other taxes are imposed on finished pharmaceutical products. Provisions for tax exceptions or waivers for pharmaceuticals and health products are in place[44].

Taxes are applied to all pharmaceuticals except that stated in the law 11 and ministerial decree 314 regarding medicines of chronic diseases and products of acdema companies (which are also duties free). Furthermore, all active ingredients are tax free, but first their companies must apply to CAPA to release ministerial decree including a list of this materials.

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 Egypt.

7.1 Public Sector Procurement

Public sector procurement in Egypt is both centralized and decentralized.[45]
The public sector procurement is centralized under the responsibility of a procurement agency which is part of MoH[46]. It is centralized for hospitals, health units and Medical Convoys of MoH. The national procurement agency is not responsible for the procurement of university hospitals which follow the Ministry of Higher Education.

Public sector request for tender documents are publicly available and public sector tender awards are publicly available. Procurement is based on the prequalification of suppliers[47]. A team from the procurement department made an inspection visit in 2007 to different drug suppliers. According to this prequalification criteria then fed the data in a database in IT of MoH. Any supplier

must fill the required criteria in this database before the application to a procurement process and any changes or addition regarding their data collected in this database.

There is a written public sector procurement policy. This policy was approved in 1998. Legal provisions exist that give priority to locally produces goods in public procurement. The key functions of the procurement unit and those of the tender committee are not clearly separated.[48] A process exists to ensure the quality of products that are publicly procured. 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.

7.2 Public Sector Distribution

The government supply system department in Egypt has a Central Medical Store at National Level also known as “General Administration of Medical Supplement”[49]. There are 194 public warehouses in the secondary tier of the public sector distribution. There are national guidelines on Good Distribution Practices (GDP). A licensing authority that issues GDP licenses exists[23] [50].

The licensing authority does not accredit public distribution facilities.

A list of GDP certified wholesalers and distributors does not exist in the public sector.

7.3 Private Sector Distribution

Legal provisions exist for licensing wholesalers and distributors in the private sector. A list of GDP certified wholesalers and distributors exists in the private sector[50] [51].

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 Egypt.

8.1 National Structures

A National Essential Medicines List (EML) exists.
The EML was lastly updated in 2006 and is publicly available.
There are currently 500 medicines on the EML. Selection of medicines for the EML is not undertaken through a written process. A mechanism aligning the EML with the Standard Treatment Guidelines (STGs) is in place[52].

National Standard Treatment Guidelines (STGs) for the most common illnesses are produced/endorsed by the MoH in Egypt. These were last updated in 2010. Specific STGs cover primary care (updated in 2008), secondary care (updated in 2006), and paediatric conditions (updated in 2010.[11] [52]

Of the public health facilities, 41.2 % have a copy of the EML and 26.5 % have a copy of the STGs.[53]

There is no public or independently funded national medicines information centre providing information on medicines to prescribers, dispensers and consumers. A survey on rational use of medicines has been conducted in the previous two years[54]. 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 does not exist.

Egypt's Essential Medicines List (EML) includes formulations specifically for children. Criteria for the selection of medicines to the EML not explicitly documented.[10] 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 exists.

A national reference laboratory or other institution does not have 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 dispense medicines.[9]

There are regulations requiring hospitals to organize/develop Drug and Therapeutics Committees (DTCs)[13].

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

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

Mandatory continuing education that includes pharmaceutical issues is not required for doctors/nurses/paramedical staff.

Prescribing by INN name is obligatory in the public sector.[13] The average number of medicines prescribed per patient contact in public health facilities is 2.3. Of the medicines prescribed in the outpatient public health care facilities, 88.47 % are on the national EML and 37.5 % are prescribed by INN name. Of the patients treated in the outpatient public health care facilities, 49.8 % receives antibiotics and 13.2 % receive injections. Of prescribed drugs, 91.2 % are dispended to patients. Of medicines in public health facilities, 45.2 % 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)	88.47
% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)	37.5
% of patients in outpatient public health care facilities receiving antibiotics (mean)	49.8
% of patients in outpatient public health care facilities receiving injections (mean)	13.2
% of prescribed drugs dispensed to patients (mean)	91.2
% of medicines adequately labeled in public health facilities (mean)	45.2

A professional association code of conduct which governs the professional behaviour of doctors exists.[9]

8.3 Dispensing

Legal provisions in Egypt exist to govern dispensing practices of pharmaceutical personnel.10 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	No
Use of STGS	Yes
Drug information	Yes
Clinical pharmacology	Yes
Medicines supply management	No

Mandatory continuing education that includes rational use of medicines is not required for pharmacists.

Substitution of generic equivalents at the point of dispensing is allowed in public and private sector facilities[13]. Sometimes antibiotics are sold over-the-counter without a prescription. Sometimes injectable medicines are sold over-the-counter without a prescription.

A professional association code of conduct which governs the professional behaviour of pharmacists exists.[8]

List of key reference documents:

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[4] NHA 2009, MOH 2011

[5] Calculated based on data provided in WHS 2011 and NHA 2007-2008

[6] Calculated based on data provided in WHS 2011 and NHA 2007-2008

[7] National Health Accounts Egypt 2007-2008, Available at: http://www.who.int/nha/country/egy/en/,30-06-2011.

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[21] Minister Decree No. 26/2009: Fees of Services provided by CAPA, EDA, available at http://www.eda.mohp.gov.eg/Download/Docs/Decree_26_2009.pdf , 2011-12-20.

[22] Decree 281, EDA website,

[23] Minister Decree No. 25/2009: Regulations of Wholesale Stores, available http://www.eda.mohp.gov.eg/Download/Docs/New_Minister_Decree_for_Wholesalers.pdf

[24] Decree 132, EDA,

[25] Decree 539, EDA, http://www.eda.mohealth.gov.eg/Download/Docs/Minister_Decree_539_Both.pdf,

[26] Minister Decree for Wholesalers, http://www.eda.mohealth.gov.eg/Download/Docs/New_Minister_Decree_for_Wholesalers.pdf

[27] EDA Website: regarding legal provision requiring pharmacists to be registered, see EDA website, available at: http://www.eda.mohp.gov.eg/Services/Pharma_Services.aspx?Main=Services&Serviceid=1&Submain=serv3 (Pharmacists Certificates, available in Arabic);

Licensing of public pharmacies, see http://www.eda.mohp.gov.eg/Download/Docs/380.pdf (available in Arabic)

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Law 32 for year 1975 for government employees
Law 99 for year 99 for students
Law 380 for year 1997 for neonates.

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314 for year 1992
38 for year 1993
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[46] Information provided by Dr Rasha Aboshady, Head of the Procurement Department (2011)

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[49] Dr Mohammed Ali, Manager of General Administration of Medical Supplement

[50] Minister Decree No. 380/2009: Specifications of Pharmacies and Stores, available at: http://www.eda.mohp.gov.eg/Download/Docs/380.pdf , 20-1-2012

[51] Pharmacy Law 127 for year 1955, code 40-45.

[52] WHO Level 1 survey (2006) and The reference is Central Administeration of Pharmaceutical Affairs (CAPA) - procurement department. The responsible person is Dr. Rasha Aboshady (2011). There is a mechanism to align the EML with the (STG) especially in oncology medicines.

There is committee on facilities level to monitor drugs utilization, following of clinical guidelines beginning in 2002 and still until now.

[53] WHO essential drugs and medicines policy (2008)

[54] Central Administration of Pharmaceutical Affairs (CAPA)-EPVC-MOH (2010)

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Pharmaceutical Sector Country Profile Questionnaire

EGYPT

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..

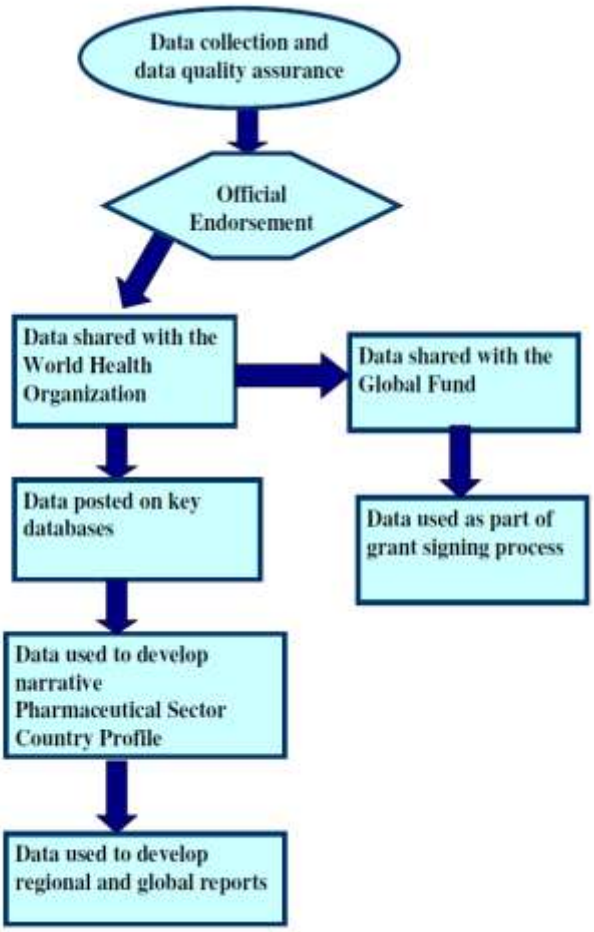
V) The data collected could be transformed into a narrative report with robust data analysis and bibliographic references, that will summarize the medicines situation in the country.

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

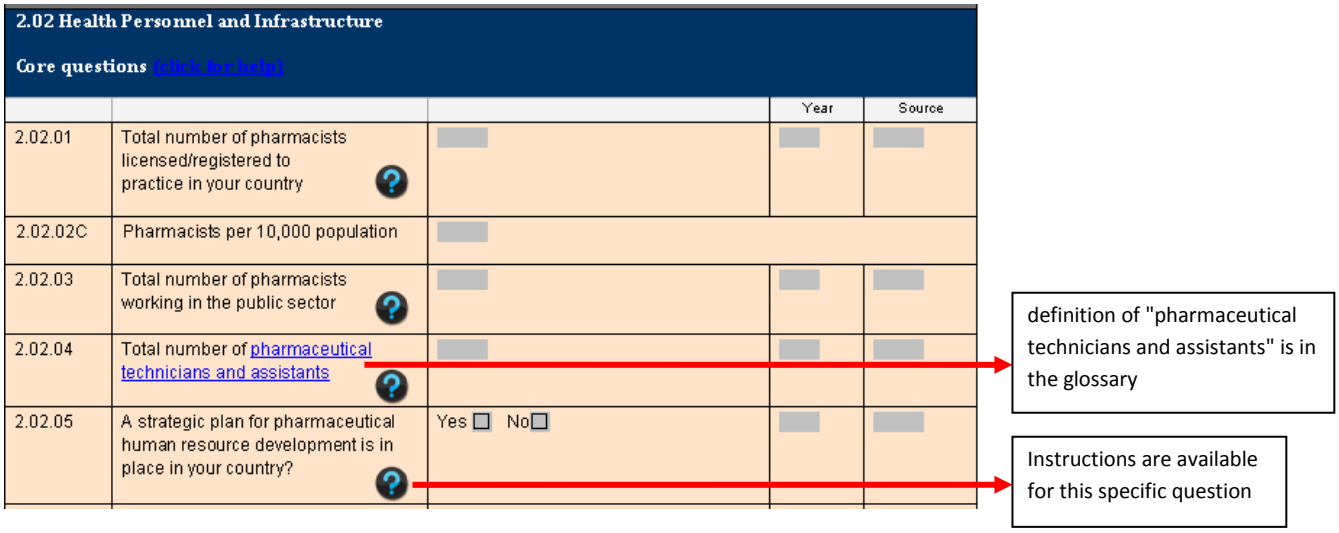
These documents will be published on the WHO web site's medicines library (http://apps.who.int/medicinedocs/en/) and will therefore have to be endorsed by the Ministry of Health prior to being made publicly available. You can send us these documents by e-mail as attachments or you can upload them into 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.

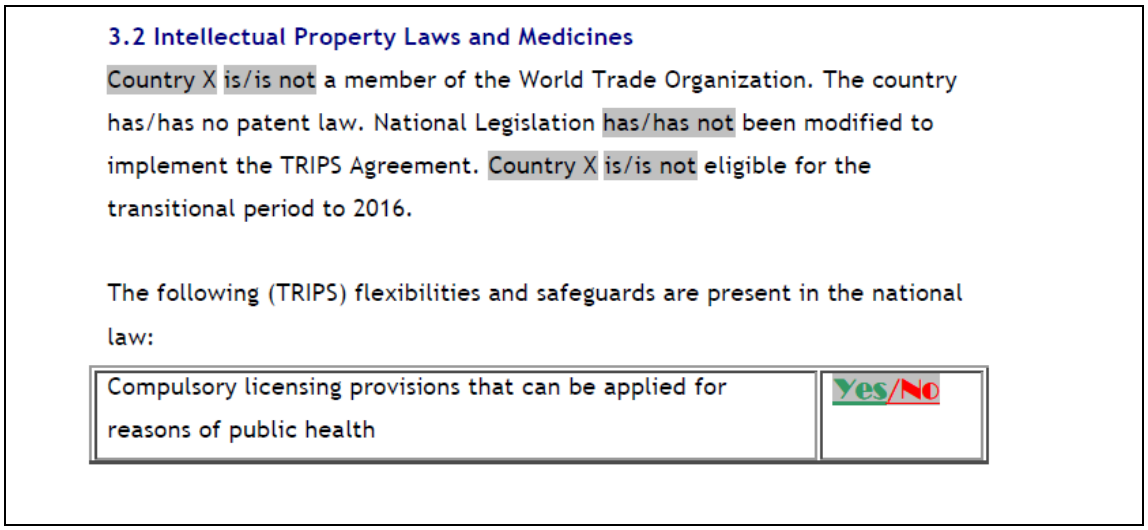


13. Respondents and acknowledgements: at the beginning of every section there are fields available to fill in details about the respondent for that particular section. It is also possible to enter the details of multiple respondents. At the end of the instrument please add a list of contributors who 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)	Egypt-RV
0.01.02	Name coordinator	
0.01.03	Address (Street, City)	21 Abd-El-Aziz Al soud
0.01.04	Phone number	+25354100
0.01.05	Email address	hosprx@eda.mohealth.gov.eg
0.01.06	Web address	www.eda.mohealth.gov.eg
0.01.07	Institution	Central Administration for Pharmaceutical Affairs (CAPA)

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	safa hassan nada
1.00.02	Phone number	0113535967
1.00.03	Email address	safa_nada1987@yahoo.com
1.00.04	Other respondents for filling out this section	Information Center Technical Office of Ministry of Health

1.01 Demographic and Socioeconomic Indicators

Core questions (click here for help)

			Year	Source
1.01.01	Population, total (,000)	82,999	2009	WHS2011
1.01.02	Population growth rate (Annual %)	1.9	2009	WHS2011
1.01.03	Total Gross Domestic Product (GDP) (millions US$)	188,412	2009	World Bank 2011
1.01.04	GDP growth (Annual %)	4.6	2009	World Bank 2011
1.01.05C	GDP per capita (US$ current exchange rate)	2,270	2009	Worldbank 2011
1.01.06	Comments and References	World Health Statistics (World Health Survey) http://www.who.int/whosis/whostat/EN_WHS2011_Full.pdf 1.01.01-Population total (,000) Page 154 1.01.02-Population growth rate (Annual %) Page 154 World Bank Data 1.01.03-Total Growth Domestic Product (GDP) (million US) http://data.worldbank.org/country/egypt-arab-republic 1.01.04- GDP growth (annual%)http://search.worldbank.org/data		

Supplementary questions (click here for help)				
			Year	Source
1.01.07S	Population < 15 years (% of total population)	32	2009	WHS 2011
1.01.08S	Population > 60 years (% of total population)	7	2009	WHS 2011
1.01.09S	Urban population (% of total population)	43	2009	WHS2011
1.01.10S	Fertility rate, total (Births per woman)	2.8	2009	WHS2011
1.01.11S	Population living with less than $1.25/day (international PPP) (%)	2.00	2005	World Bank data2011
1.01.12S	Population living below nationally defined poverty line (%)	16.7	2000	World Bank data2011
1.01.13S	Income share held by lowest 20% of the population (% of national income)	9	2005	World Bank data2011
1.01.14S	Adult literacy rate, 15+ years (% of relevant population)	66	2008	WHS2011
1.01.15S	Comments and References	World Health Statistics (World Health Survey) http://www.who.int/whosis/whostat/EN_WHS2011_Full.pdf 1.01.07S-Population < 15 years (% of total population) Page 154 1.01.08S- Population> 60 years (%of total population) Page 154 1.01.09S- Urban population (% of total population) Page 154 1.01.10S- Fertililty rate, total (Births per woman) Page 155 World Bank Data		

1.02 Mortality and Causes of Death Core questions (click here for help)				
			Year	Source
1.02.01	Life expectancy at birth for men	69	2009	WHS2011

	(Years)			
1.02.02	Life expectancy at birth for women (Years)	73	2009	WHS2011
1.02.03	Infant mortality rate, between birth and age 1 (/1,000 live births)	18	2009	WHS2011
1.02.04	Under 5 mortality rate (/1,000 live births)	21	2009	WHS2011
1.02.05	Maternal mortality ratio (/100,000 live births)	82	2008	WHS 2011
1.02.06	Please provide a list of top 10 diseases causing mortality		2010	Ministery of Health 2011 (ref attached)
1.02.06.01	Disease 1	Essential primary Hypertension		
1.02.06.02	Disease 2	Intracerebral Haemorrhage		
1.02.06.03	Disease 3	Fibrosis and cirrhosis of liver		
1.02.06.04	Disease 4	Hepatic Failure		
1.02.06.05	Disease 5	Atherosclerosis		
1.02.06.06	Disease 6	Elevated Blood Glucose level		
1.02.06.07	Disease 7	Arterial Embolisim and thrombosis		
1.02.06.08	Disease 8	Acute myocardial infarction		
1.02.06.09	Disease 9	Cerebral infarction		
1.02.06.10	Disease 10	other		
1.02.07	Please provide a list of top 10 diseases causing morbidity		2010	Ministery of Health 2011
1.02.07.01	Disease 1	Infectious Gastroenteritis		
1.02.07.02	Disease 2	Spontaneous Labor		

1.02.07.03	Disease 3	Caesarean section
1.02.07.04	Disease 4	Acute appendicitis
1.02.07.05	Disease 5	Iron deficiency anemia
1.02.07.06	Disease 6	Respiratory Distress Syndrome (RDS)
1.02.07.07	Disease 7	Broncho pneumonia
1.02.07.08	Disease 8	Acute tonsillitis
1.02.07.09	Disease 9	Forearm Fracture
1.02.07.10	Disease 10	Non specific renal colic
1.02.08	Comments and References	World health statistics (World Health Survey) http://www.who.int/whosis/whostat/EN_WHS2011_full.pdf 1.02.01-Life expectancy at birth for men (years) Page 48 1.02.02-Life expectancy at birth for woman (years) Page 48 1.02.03-Infant mortality rate between birth and age1 (/ 100,000 live births) Page 49 1.02.04-Under 5 mortality rate (/ 1,000 birth rate) Page 49 1.02.05-Maternal Mortality Ratio (/ 100,000 live births) Page 62 1.02.05-Maternal Mortality Ratio value is 82 (51-130) 1.02.05-Maternal Mortality Ratio value was brought from WHS (2011) not from WHS- interagency est 1.02.07.-Concerning Top 10 Morbidity diseases in Egypt questions: Actually they are top 15 diseases and 45.8% of the in patients discharged having those diseases in general and central hospitals. The rest of the 5 top morbidity diseases are: -Liver cirrhosis -Heart Failure -Essential Hypertension

		-Bronchitis -Assissted Labor The refrences of such morbidity diseases: Ministery of Health (MOH) 1.02.06- concerning the top 10 diseases of mortality in Egypt: Refrences From Ministery of Health		
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)	174	2009	WHS2011
1.02.10S	Neonatal mortality rate (/1,000 live births)	11	2009	WHS2011
1.02.11S	Age-standardized mortality rate by non-communicable diseases (/100,000 population)	749	2008	WHS2011
1.02.12S	Age-standardized mortality rate by cardiovascular diseases (/100,000 population)	515	2009	WHS2011
1.02.13S	Age-standardized mortality rate by cancer (/100,000 population)	81	2009	WHS2011
1.02.14S	Mortality rate for HIV/AIDS (/100,000 population)	0.6	2009	WHS2011
1.02.15S	Mortality rate for tuberculosis (/100,000 population)	1.1	2009	WHS2011
1.02.16S	Mortality rate for Malaria (/100,000 population)	0.2	2008	WHS2011
1.02.17S	Comments and References	World health statistics (World Health Survey) http://www.who.int/whosis/whostat/EN_WHS2011_Full.pdf 1.02.09S-Adult mortality rate for both sexes between 15 and 60 years of age (/ 1000 population) Page 49		

		1.02.10S-Neonatal mortality rate (/ 1000 live births).Page 48 1.02.11S-Age standardized mortality rate by non communicable diseases (/ 100,000 population).Page 63 1.02.14S- Mortality rate for HIV/AIDS among (/ 100,000 population) Page 62 1.02.14S-* Mortality rate for HIV/AIDS value is 0.6 [0.5-0.9] 1.02.15S- Mortality rate for tuberculosis (/ 100,000 population) among HIV negative.Page 62 1.02.15S-Mortality rate for tuberculosis value is 1.1 [0.7-1.5] 1.02.16S- Mortality rate for Malaria (/ 100,000 population). Page 62 1.02.16SThe value of mortality rate for malaria (/100,000 population) is 0.2 [0.1-0.2]

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	Zahraa Hassan Abdelrahman
2.00.02	Phone number	202 0106500898
2.00.03	Email address	funnypharm7@hotmail.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)	61,400	2009	NHA 2011
2.01.01.02	Total annual expenditure on health (millions US$ average exchange rate)	10,962	2009	average Exchange rate 2009: 5.601
2.01.02C	Total health expenditure as % of Gross Domestic Product	5.8		
2.01.03.01C	Total annual expenditure on health per capita (NCU)	740		
2.01.03.02C	Total annual expenditure on health per capita (US$ average exchange rate)	132		
2.01.04.01	General government annual expenditure on health (millions NCU)	15,200	2009	NHA
2.01.04.02	General government annual expenditure on health (millions US$ average exchange rate)	2,576	2009	Exchange rate 5/8/2011
2.01.05	Government annual expenditure on health as percentage of total government budget (% of total	4.3	2009	NHA data

	government budget)			
2.01.06C	Government annual expenditure on health as % of total expenditure on health (% of total expenditure on health)	24.76	2009	NHA
2.01.07.01C	Annual per capita government expenditure on health (NCU)	183.13		
2.01.07.02C	Annual per capita government expenditure on health (US$ average exchange rate)	32.69		
2.01.08C	Private health expenditure as % of total health expenditure (% of total expenditure on health)	75.24	2009	NHA 2011
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)	51	2009	NHA 2011
2.01.10	Population covered by private health insurance (% of total population)			
2.01.11.01	Total pharmaceutical expenditure (millions NCU)	21,000	2009	NHA 2011
2.01.11.02	Total pharmaceutical expenditure (millions US$ current exchange rate)	3,559.63	2099	Exchange rate 5/8/2011
2.01.12.01C	Total pharmaceutical expenditure per capita (NCU)	253		
2.01.12.02C	Total pharmaceutical expenditure per capita (US$ current exchange rate)	42.89		
2.01.13C	Pharmaceutical expenditure as a % of GDP (% of GDP)	1.89		
2.01.14C	Pharmaceutical expenditure as a % of Health Expenditure (% of total health expenditure)	34.20		

2.01.15.01	Total public expenditure on pharmaceuticals (millions NCU)	2,567	2008	NHA data
2.01.15.02	Total public expenditure on pharmaceuticals (millions US$ current exchange rate)	435.11	2008	NHA data
2.01.16C	Share of public expenditure on pharmaceuticals as percentage of total expenditure on pharmaceuticals (%)	23.31		
2.01.17.01C	Total public expenditure on pharmaceuticals per capita (NCU)	31		
2.01.17.02C	Total public expenditure on pharmaceuticals per capita (US$ current exchange rate)	5.6		
2.01.18.01	Total private expenditure on pharmaceuticals (millions NCU)	8,445.71	2008	NHA data
2.01.18.02	Total private expenditure on pharmaceuticals (millions US$ current exchange rate)	1,431.45	2008	Exchange rate 28/6/2011
2.01.19	Comments and References	2.01.01.01 NHA 2009 2.01.04.01 NHA data 2008, page 17, in this question government expenditure is considered the same as public expenditure 2.01.09 the mentioned number is the percentage of total population the absolute population number at year 2008 was 41 million (NHA page 40) - this value is percent of population covered by health insurance service only which is nearly the only type of this services 2.01.10 49% of population are unisnisured according to NHA 2009 2.01.11.01 NHA data page 17 2.01.15.01 Clear data is not available, it is calculated by subtracting value of private pharmaceutical expenditure in NHA 2008 and total pharmaceutical expenditure in NHA 2008. 2.01.18.01 NHA data 2008 page 33 in this question households are considered the private expenditure as it represnts nearly all of the private expenditure		

Supplementary questions (click for help)				
			Year	Source
2.01.20S	Social security expenditure as % of government expenditure on health (% of government expenditure on health)	26.83	2008	NHA data
2.01.21S	Market share of generic pharmaceuticals [branded and INN] by value (%)			
2.01.22S	Annual growth rate of total pharmaceuticals market value (%)	14.4	2010	IMS 2011
2.01.23S	Annual growth rate of generic pharmaceuticals market value (%)			
2.01.24S	Private out-of-pocket expenditure as % of private health expenditure (% of private expenditure on health)	95.14	2008	NHA data
2.01.25S	Premiums for private prepaid health plans as % of total private health expenditure (% of private expenditure on health)	0.22	2008	NHA data
2.01.26S	Comments and References			

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	139,479	2011	Egyptian pharmacy syndicate
2.02.02C	Pharmacists per 10,000 population	16.8		
2.02.03	Total number of pharmacists working in the public sector	15,457	2011	MOH

2.02.04	Total number of pharmaceutical technicians and assistants			
2.02.05	A strategic plan for pharmaceutical human resource development is in place in your country?	Yes ☒ No ☐	2011	MOH-CAPA
2.02.06	Total number of physicians	223,203	2011	Egyptian medical syndicate
2.02.07C	Physicians per 10,000 pop	27		
2.02.08	Total number of nursing and midwifery personnel	280,561	2009	WHS 2011
2.02.09C	Nurses and midwives per 10,000 pop	35.2		
2.02.10	Total number of hospitals	1,969	2010	MOH 2011
2.02.11	Number of hospital beds per 10,000 pop	15.49	2010	MOH 2011
2.02.12	Total number of primary health care units and centers	5034	2010	MOH 2011
2.02.13	Total number of licensed pharmacies	59,798	2010	CAPA-MOH 2011
2.02.14	Comments and References	2.02.01: Attached reference from database of egyptian pharmacy syndicate (licensed pharmacist must be a member in the syndicate)- The responsible person are Mr. Emad Faisal Mohamed (lawyer) Tel:: 002 02 27958394 2.02.03: This number may be slightly lower than the actual number because a small number work in miscellaneous public jobs and are included in any total database. 2.02.04: There isn't any educational institution who teaches this profession and certifies the graduates however thousands of persons (with no certain reqiurements) do these tasks in community pharmacies 2.02.05: The reference is central adminstration of pharmaceutical affairs at ministry of health departement of QA and training the responsible person is Dr.Heba mostafa telephone: 25354100- attached document is the objectives of development however this		

		objectives not yet made into a plan 2.02.06: The attached refernce from egyptian medical syndicate- the responsible person is Mr.Ahmed Morsy. Tel.: 002 02 27940738 2.02.08 There is no license or education for midwifery but for nurses the data available in the syndicate- we contacted them several times but no reply 2.02.11: Attached reference is from ministry of health- The written no. is the total number of beds per 10.000 population while the absolute total no. is 128573 beds 2.02.13: The mentioned number is only the community pharmacies without the hospital pharmacies because there is no complete database on hopital pharmcies

Supplementary questions (click here for help)

			Year	Source
2.02.15S	Starting annual salary for a newly registered pharmacist in the public sector (NCU)	13,800	2011	Financial Adminstration- CAPA-MOH
2.02.16S	Total number of pharmacists who graduated (first degree) in the past 2 years in your country			
2.02.17S	Are there accreditation requirements for pharmacy schools?	Yes ☒ No☐	2011	Supreme Council of Universities
2.02.18S	Is the Pharmacy Curriculum regularly reviewed?	Yes ☒ No ☐	2011	Supreme Council of Universities
2.02.19S	Comments and References	2.02.15S: This number is calculated in (NCU)- This value is the mean for the salary the range is 700-1500 NCU		

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	Andrew Botros Saleh Metry		
3.00.02	Phone number	0020177386295		
3.00.03	Email address	andrew_aswan@hotmail.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 ☐	2005	Health System Profile Egypt
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 ☐	2006	Health System Profile Egypt
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 ☐	2005	WHO level I
3.01.05	Group of policies addressing pharmaceuticals exist.	Yes ☒ No ☐	2009	Pharmacy policies and procedures, Health Insurance Information

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 ☒		WHO level I
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 ☒		
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 ☒		
3.01.10	Access to essential medicines/technologies as part of the fulfillment of the right to health,	Yes ☒ No ☐	2009	Pharmacy policies and

	recognized in the constitution or national legislation?			procedures, Health Insurance Information
3.01.11	There are official written guidelines on medicines donations.	Yes ☒ No ☐	2007	WHO level I
3.01.12	Is pharmaceutical policy implementation being regularly monitored/assessed?	Yes ☒ No ☐	2009	Egyptian Drug Authority
3.01.12.01	Who is responsible for pharmaceutical policy monitoring?	The Egyptian Drug Authority (EDA) consisting of Central Administration of Pharmaceutical Affairs (CAPA), National Organization for Drug Control and Research (NODCAR) & National Organization For research & Control of Biologicals (NORCB)		
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 ☐	1978	Law 47 for Civilian personnel system state
3.01.15	There is a formal code of conduct for public officials.	Yes ☒ No ☐	1978	Law 47 for Civilian personnel system state
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 ☐		
3.01.16.01	Please describe:	In each Ministry in the government, there's an office for Citizen's Services, where any normal citizen can report any wrongdoing		

		occurred with him in that ministry. Then this complaint is processed for further investigation.
3.01.17	Comments and References	3.01.01: Health System Profile Egypt, Regional Health Sytem Observatory, WHO, 2006. available at: http://gis.emro.who.int/HealthSystemObservatory/PDF/Egypt/Full%20Profile.pdf 3.01.05 Pharmacy policies and procedures, Health Insurance Information (Arabic only), 2009. http://www.mohp.gov.eg/DocLib6/Pharmacy%20policies%20_%20procedures.pdf; Regarding 3.01.06.03, see Section 6 Regarding Qu 3.01.08, this is an area of increased focus and is currenmtly work in progress to finalize it's legistlation 3.01.12 Egyptian Drug Authority, http://www.eda.mohp.gov.eg/About/EDAWelcome.aspx?Main=about&aboutid=1&SubAbout=55

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	Andrew Botros Saleh Metry
4.00.02	Phone number	0020177386295
4.00.03	Email address	andrew_aswan@hotmail.com
4.00.04	Other respondents for filling out this section	Raghda Shehab Eldin Abd Ellatif

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☐	1995	WTO
4.01.02	Legal provisions provide for granting of Patents on:		2007	WHO level I
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	Egyptian Patent Office (ASRT) Addess: 101 Kasr-Eni St. Tel No.: 0020227921272		
4.01.03.02	Please provide URL	http://www.egypo.gov.eg/		
4.01.04	National Legislation has been modified to implement the TRIPS Agreement	Yes ☒ No ☐	2007	WHO level I
4.01.05	Current laws contain (TRIPS)	Yes ☒ No☐	2002	Law no. 82

	flexibilities and safeguards			
4.01.06	Country is eligible for the transitional period to 2016	Yes ☐ No☒		
4.01.07	Which of the following (TRIPS) flexibilities and safeguards are present in the national law?		2007	WHO level I
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 ☐	2007	WHO level I
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 ☐		
4.01.10	Are there legal provisions for data exclusivity for pharmaceuticals	Yes ☐ No ☒		
4.01.11	Legal provisions exist for patent extension	Yes ☐ No ☒		
4.01.12	Legal provisions exist for linkage between patent status and Marketing Authorization	Yes ☐ No ☒		
4.01.13	Comments and References	4.01.05 Intellectual Property Law No. 82, 2002. Available at: http://www.egypo.gov.eg/inner/english/PDFs/law2002e.pdf, 30-06-2011. Regarding 4.01.09, we have 3 projects with WIPO for innovation: TISC, TTO & IPAcademy		

4.02 Manufacturing **Core questions (click here for help)**		
	Year	Source

4.02.01	Number of licensed pharmaceutical manufacturers in the country	119	2011	Pharmaceutical Licensing Administration - CAPA
4.02.02	Country has manufacturing capacity		2011	Pharmaceutical Licensing Administration - CAPA
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 (%)			
4.02.04	Comments and References	There is a hardware attached document enlisting all the licensed pharmaceutical manufacturers in Egypt with their coresponding lines of production.		

Supplementary questions (click here for help)

			Year	Source
4.02.05S	Percentage of market share by volume produced by domestic manufacturers (%)			
4.02.06S	Number of multinational pharmaceutical companies manufacturing medicines locally	18	2011	Commercial Record
4.02.07S	Number of manufacturers that are Good Manufacturing Practice			

	(GMP) certified			
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	Gihan Hamdy
5.00.02	Phone number	20127366018
5.00.03	Email address	gehmasters007@yahoo.com
5.00.04	Other respondents for filling out this section	

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 ☐	2007	WHO level I
5.01.02	There is a Medicines Regulatory Authority	Yes ☒ No ☐	2007	WHO level I
5.01.03	If yes, please provide name and address of the Medicines regulatory authority	Central Administration for pharmaceutical affairs (CAPA) 21 Abd Elaziz Alsood, Rawdat Elmanial, Cairo Egypt		
5.01.04	The Medicines Regulatory Authority is:		2011	EDA website
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?		2011	EDA website

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	820	2011	CAPA
5.01.06.01	Date of response	09-06-2011		
5.01.07	The MRA has its own website	Yes ☒ No ☐	2009	WHO 2011
5.01.07.01	- If yes, please provide MRA Web site address (URL)	http://www.eda.mohp.gov.eg/		
5.01.08	The MRA receives external technical assistance	Yes ☒ No ☐	2009	EDA website decree 296
5.01.08.01	If yes, please describe:	Technical comitties formed of external professors		
5.01.09	The MRA is involved in harmonization/ collaboration initiatives	Yes ☐ No ☒	2007	WHO level I
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	WHO 2011
5.01.11	Medicines Regulatory Authority gets funds from regular budget of the	Yes ☒ No ☐	2009	EDA website

	government.			decree 26
5.01.12	Medicines Regulatory Authority is funded from fees for services provided.	Yes ☒ No ☐	2009	EDA website decree 26
5.01.13	Medicines Regulatory Authority receives funds/support from other sources	Yes ☐ No ☒		
5.01.13.01	- If yes, please specify			
5.01.14	Revenues derived from regulatory activities are kept with the Regulatory Authority	Yes ☐ No ☒	2009	EDA website decree 26
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	EDA website
5.01.16	Comments and References	5.01.11/12 http://www.eda.mohealth.gov.eg/Download/Docs/Decree_26_2009.pdf 5.01.14 (comment: 50 % from revenues to Regularity Authority) http://www.eda.mohealth.gov.eg/Download/Docs/Decree_26_2009.pdf		

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 ☐	2009	EDA website decree 296

5.02.02	Are there any mechanism for exception/waiver of registration?	Yes ☒ No ☐	2009	EDA website decree 296
5.02.03	Are there mechanisms for recognition of registration done by other countries	Yes ☒ No ☐	2009	EDA website decree 296
5.02.03.01	If yes, please explain:	under certain requirements : 1-For prescriptions only 2-Reports from physicians 3-Through Egyptian drug distribution company		
5.02.04	Explicit and publicly available criteria exist for assessing applications for Marketing Authorization of pharmaceutical products	Yes ☒ No ☐	2009	EDA website decree 296
5.02.05	Information from the prequalification programme managed by WHO is used for product registration	Yes ☒ No ☐	2009	EDA website decree 296
5.02.06	Number of pharmaceutical products registered in your country	8,973	2011	EDA website
5.02.07	Legal provisions require the MRA to make the list of registered pharmaceuticals with defined periodicity publicly available	Yes ☒ No ☐	2009	EDA website decree 296
5.02.07.01	If yes, how frequently updated	every 10 years		
5.02.07.02	If yes, please provide updated list or URL *	http://www.eda.mohealth.gov.eg/Services/Drug_Hum.aspx?Main=Services&Serviceid=2&Submain=serv7		
5.02.08	Medicines registration always includes the INN (International Non-proprietary Names)	Yes ☒ No ☐	2011	EDA website
5.02.09	Legal provisions require the payment of a fee for Medicines Marketing	Yes ☒ No ☐	2009	EDA website

	Authorization (registration) applications			decree 26
5.02.10	Comments and References	5.02.04 http://www.eda.mohealth.gov.eg/Services/Drug_Hum.aspx?Main=Services&Serviceid=2&Submain=serv7 5.02.01/2/5/7 http://www.eda.mohealth.gov.eg/Download/Docs/MinisterDec296.pdf 5.02.06 8973 pharmaceutical products + 379 Biological products 5.02.08 http://www.eda.mohealth.gov.eg/Services/Drug_Hum.aspx?Main=Services&Serviceid=2&Submain=serv7		
Supplementary questions (click here for help)				
			Year	Source
5.02.11S	Legal provisions require Marketing Authorization holders to provide information about variations to the existing Marketing Authorization	Yes ☒ No ☐	2009	EDA website decree 296
5.02.12S	Legal provisions require publication of a Summary of Product Characteristics (SPCs) of the medicines registered	Yes ☒ No ☐	2009	EDA website decree 296
5.02.13S	Legal provisions require the establishment of an expert committee involved in the marketing authorization process	Yes ☒ No ☐	2009	EDA website decree 296
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 ☒	2009	EDA website decree 296
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 ☐	1978	decree 47

5.02.16S	Legal provisions allow applicants to appeal against MRAs decisions	Yes ☒ No ☐	2009	EDA website decree 296
5.02.17S	Registration fee - the amount per application for pharmaceutical product containing New Chemical Entity (NCE) (US$)	1,675	2009	EDA website decree 26
5.02.18S	Registration fee - the Amount per application for a generic pharmaceutical product (US$)	1,675	2009	EDA website decree 26
5.02.19S	Time limit for the assessment of a Marketing Authorization application (months)	12	2009	EDA website decree 296
5.02.20S	Comments & References	5.02.14s CPP required for imported drugs only 5.02.17s, 5.02.18s date of exchange 28/6/2011 5.02.19s it depend on other factors		

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 ☐	1994	EDA website decree 281
5.03.02	Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed	Yes ☒ No ☐	2007	WHO level I
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		2009	EDA

	licensing of:	Yes ☒		website decree 25
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 ☐	2009	EDA website decree 25
5.03.05.01	Local manufactures are inspected for GMP compliance	Yes ☒ No ☐	2007	WHO level I
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 and unexpected inspection		
5.03.06	Comments and References	5.03.04 Inspection requirements are the same except: 1- The expired drugs in the public facilities are not present however in private facilities they present in isolated place until returned to suppliers. 2- Inspection on Inventory present in public facilities only.		

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 ☐	1994	EDA website

				decree 132
5.04.02	Legal provisions exist allowing the sampling of imported products for testing	Yes ☒ No ☐	1994	EDA website decree 132
5.04.03	Legal provisions exist requiring importation of medicines through authorized ports of entry	Yes ☒ No ☐	1994	EDA website decree 132
5.04.04	Legal provisions exist allowing inspection of imported pharmaceutical products at the authorized ports of entry	Yes ☐ No ☒		
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	WHO level I
5.05.02	Legal provisions exist requiring both domestic and international manufacturers to comply with Good manufacturing Practices (GMP)	Yes ☒ No ☐	2007	EDA website decree 539
5.05.02.01	If no, please explain			
5.05.03	GMP requirements are published by the government.	Yes ☒ No ☐	2007	EDA website decree 539
5.05.04	Legal provisions exist requiring importers to be licensed	Yes ☒ No ☐	2007	WHO level I
5.05.05	Legal provisions exist requiring wholesalers and distributors to be licensed	Yes ☒ No ☐	2009	EDA website decree 25
5.05.06	Legal provisions exist requiring wholesalers and distributors to	Yes ☒ No ☐	2009	EDA

	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)**			website decree 25
5.05.07	National Good Distribution Practice requirements are published by the government	Yes ☒ No ☐	2009	EDA website decree 25
5.05.08	Legal provisions exist requiring pharmacists to be registered	Yes ☒ No ☐	2011	EDA website
5.05.09	Legal provisions exists requiring private pharmacies to be licensed	Yes ☒ No ☐	2011	EDA website
5.05.10	Legal provision exist requiring public pharmacies to be licensed	Yes ☒ No ☐	2011	EDA website
5.05.11	National Good Pharmacy Practice Guidelines are published by the government	Yes ☒ No ☐	2011	EDA website
5.05.12	Legal provisions require the publication of a list of all licensed pharmaceutical facilities	Yes ☒ No ☐	2011	EDA website
5.05.13	Comments and References	5.05.02 http://www.eda.mohealth.gov.eg/Download/Docs/Minister_Decree_539_Both.pdf 5.05.05/06 http://www.eda.mohealth.gov.eg/Download/Docs/New_Minister_Decree_for_Wholesalers.pdf 5.05.12 There is database in every Directorate		

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 ☐	2009	EDA website decree 296
5.06.02	Does a laboratory exist in the country for Quality Control testing?	Yes ☒ No ☐	2011	EDA website
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	National Organization For research & Control of Biologicals Ensure the Safety, quality and efficacy of all imported and domestic Biologicals in Compliance with WHO requirements & international organization for standardization		
5.06.03	Is there any national laboratory accepted for collaboration with WHO prequalification Programme? Please describe.	yes National Oganization for Drug Control and Research (NODCAR)		
5.06.04	Medicines are tested:		2009	EDA website decree 296
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	Yes ☒ No ☐		

	prequalification			
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	WHO level I
5.06.06	How many Quality Control samples were taken for testing in the last two years?	48706	2010	NODCAR report
5.06.07	Total number of samples tested in the last two years that failed to meet quality standards	277	2010	NODCAR report
5.06.08	Results of quality testing in past two years are publicly available	Yes ☐ No ☒	2011	NODCAR report
5.06.09	Comments and References	5.06.01 http://www.eda.mohealth.gov.eg/Download/Docs/MinisterDec296.pdf		

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 ☐	2008	Decree 106
5.07.02	Who is responsible for regulating, promotion and/or advertising of medicines? Please describe:	Medicnes Regulatory Authority (Central Administration for Pharmaceutical Affairs) responsible for reviewing scientific and marketing materials		
5.07.03	Legal provisions prohibit direct advertising of prescription medicines to the public	Yes ☒ No ☐	2008	Decree 106
5.07.04	Legal provisions require a pre-approval for medicines	Yes ☒ No ☐	2007	WHO level

	advertisements and promotional materials 			I
5.07.05	Guidelines/Regulations exist for advertising and promotion of non-prescription medicines	Yes ☒ No ☐	2007	WHO level I
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 ☐		
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	Yes ☐ No ☒		

	Trials by the MRA			
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 ☒		
5.08.03	Legal provisions exist requiring registration of the clinical trials into international/national/regional registry	Yes ☐ No ☒		
5.08.04	Comments and References	Work in progress , and active steps are being taken for soon implementation		
Supplementary questions (click here for help)				
			Year	Source
5.08.05S	Legal provisions exist for GMP compliance of investigational products	Yes ☐ No ☒		
5.08.06S	Legal provisions require sponsor, investigator to comply with Good Clinical Practices (GCP)	Yes ☐ No ☒		
5.08.07S	National GCP regulations are published by the Government.	Yes ☐ No ☒		
5.08.08S	Legal provisions permit inspection of facilities where clinical trials are performed	Yes ☐ No ☒		
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 ☐	1966	International Narcotics Control Board

5.09.01.02	The 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	Yes ☒ No ☐	1974	International Narcotics Control Board
5.09.01.03	Convention on Psychotropic Substances 1971	Yes ☒ No ☐	1972	International Narcotics Control Board
5.09.01.04	United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	Yes ☒ No ☐	1991	International Narcotics Control Board
5.09.02	Laws for the control of narcotic and psychotropic substances, and precursors exist	Yes ☒ No ☐	2009	EDA website Decree 350
5.09.03	Annual consumption of Morphine (mg/capita)	0.2195122	2011	International Narcotics Control Board
5.09.04	Comments and References	5.09.02 http://www.eda.mohealth.gov.eg/Download/Docs/Decree350.pdf		

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 WHO International Expert or Partner Organization to assess the balance between the prevention of abuse and access for medical need	Yes ☐ No ☒ Unknown ☐		
5.09.05.01S	If yes, year of review			
5.09.06S	Annual consumption of Fentanyl (mg/capita)	0.02439024	2011	International Narcotics Control Board

5.09.07S	Annual consumption of Pethidine (mg/capita)	1.09756098	2011	International Narcotics Control Board
5.09.08S	Annual consumption of Oxycodone (mg/capita)	0.0304878	2011	International Narcotics Control Board
5.09.09S	Annual consumption of Hydrocodone (mg/capita)	0.06097561	2011	International Narcotics Control Board
5.09.10S	Annual consumption of Phenobarbital (mg/capita)	73.1707317	2011	International Narcotics Control Board
5.09.11S	Annual consumption of Methadone (mg/capita)	0.01219512	2011	International Narcotics Control Board
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 ☐	1995	Decree 397
5.10.02	Legal provisions exist requiring the Marketing Authorization holder to continuously monitor the safety of their products and report to the MRA	Yes ☒ No ☐	2010	Decree 2
5.10.03	Legal provisions about monitoring Adverse Drug Reactions (ADR) exist in your country	Yes ☒ No ☐	1995	Decree 397

5.10.04	A national pharmacovigilance centre linked to the MRA exists in your country	Yes ☒ No ☐	2010	Decree 2
5.10.04.01	If a national pharmacovigilance centre exists in your country, how many staff does it employ full-time	7		
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	Egyptian Pharmaco Vigilance Center (EPVC)
5.10.06	A national Adverse Drug Reactions database exists in your country	Yes ☒ No ☐	2011	EPVC
5.10.07	How many ADR reports are in the database?	91	2011	EPVC
5.10.08	How many reports have been submitted in the last two years?	91	2011	EPVC
5.10.09	Are ADR reports sent to the WHO database in Uppsala?	Yes ☐ No ☒		
5.10.09.01	If yes, number of reports sent in the last two years			
5.10.10	Is there a national ADR or pharmacovigilance advisory committee able to provide technical assistance on causality assessment,	Yes ☒ No ☐	2010	Decree 2

	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	Recruiting and training more staff Finalize our regulatory pharmacovigilance guidelines Implementation of pharmacovigilance training on larger scale for pharmaceutical companies and healthcare proffesionals Expanding the awareness campaign to all governates Expand speciality of EPVC to include medication errors		
5.10.14	Comments and References	5.10.03 but reporting for healthcare professionals is optional not mandatory 5.10.04.01 6 pharmacists, 1 administrative assistant 5.10.04.02 The National center established in january 2010 5.10.05 http://www.epvc.gov.eg/images/Downloads/F_12.pdf 5.10.09. not yet 5.10.11 under development as part of EPVC guidelines		
Supplementary questions (click here for help)				
			Year	Source
5.10.15S	Feedback is provided to reporters	Yes ☒ No ☐	2011	EPVC
5.10.16S	The ADR database is computerized	Yes ☒ No ☐	2011	EPVC

5.10.17S	Medication errors (MEs) are reported	Yes ☐ No ☒		
5.10.18S	How many MEs are there in the ADRs database?			
5.10.19S	There is a risk management plan presented as part of product dossier submitted for Marketing Authorization?	Yes ☒ No ☐	2011	EPVC
5.10.20S	In the past two years, who has reported ADRs?		2011	EPVC
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	EPVC
5.10.22S	Are there training courses in pharmacovigilance?	Yes ☒ No☐	2011	EPVC
5.10.22.01S	If yes, how many people have been trained in the last two years?	2440	2011	EPVC
5.10.23S	Comments and References	5.10.17S not yet but intended in future expansion 5.10.21S concerning poor quality products		

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	raghda shehab elden abd elateef
6.00.02	Phone number	0020121468362
6.00.03	Email address	dr_raghda87@hotmail.com
6.00.04	Other respondents for this sections	dr sawsan asaad general manager of pharmacy in HIO dr maiada in pricing department dr fatma in pricing department DR ASHRAF KAMEL HEAD OF PRICING DEPARTMENT dr hossam head of general pharmacy inspection dr shimaa head of import approvals dr moniur shokry MOH consultant

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:		2011	HIO
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	curative care free of charge treatment is offered by MOH curative sector which covers 530 hospitals across egypt ,this hospitals contain specialities more than that in HIO hospitals , for children under 5 a request is offered where a card is offered to give treatment free and it is expired after completing 6 years,elderly over 60 years offer a request from pensione organization with birth certificate		

6.01.02	Is there a public health system or social health insurance scheme or public programme providing medicines free of charge for :		2011	HIO
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	for antibilharzial and hepatitis C medicines		
6.01.02.09	Please describe/explain your yes answers for questions above	because this medicines related to endemic diseases in egypt		
6.01.03	Does a national health insurance, social insurance or other sickness fund provide at least partial medicines coverage?	Yes ☒ No ☐	2001	ministerial decree number 1966 2011
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	There are four broad classes of HIO beneficiaries: 1) Employees covered through Law 32 of the year 1975 (all employees working in the government sector). 2) Employees covered through Law 79 of 1975 (some public and		

		private sector employees), and pensioners and widows. 3) Beneficiaries of the Student Health Insurance Program (SHIP) by law number 99 for year1992 and covering more than 14 million students, thus increasing the total beneficiary population from 4.895 million in 1992 to 20.67 million in 1995 (Egypt National Health Accounts, 1995). 4) Newly-born children up to age five years, according to ministerial decree number 380 for the year 1997an action that has increased the beneficiary population by some 9 million, to include approximately 55% of the Egyptian population.		
6.01.04	Do private health insurance schemes provide any medicines coverage?	Yes ☒ No ☐	2006	attached health system profile egypt 2011 look title of private insurance programms ,trends ,eligibility
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	regarding question 6.01.02.01, 6.03.01 they offer coverage for EML of HIO question 6.01.03.03 also from health system profile egypt 2006		

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 ☒	1975	law 79 for pensioners , law 32 for governmen t employee,

				law 99 for students, law 380 for neonates
6.02.02	In your health system, at the point of delivery, are there any co-payment/fee requirements for medicines	Yes ☒ No ☐	1975	law 79 for pensioners , law 32 for governmen t employee, law 99 for students, law 380 for neonates
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 ☒		
6.02.03.01	Please describe the patient fees and copayments system	according to the laws mentioned above , for pensioners pay 1% of their salaries for insurance for consultations and medicines in HIO hospitals and receive consultations and medicines for free , for government employee pay 0.5% of their salaries but pays about 1L.E for receiving medicines only , students pay 12L.E with School fees		
6.02.04	Comments and References	for question 6.02.01 and 6.02.02 law 79 for year 1975 for pensioners , law 32 for year1975 for government employee, law 99 for year 1992, law 380 for year 1997		

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 ☐	2009	minsterial decree number 373 , 314 , 38 ,

				150, , 313 2011
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.)	These provisions applied to all types of medicines in the market generics , originater, EML		
6.03.02	Government runs an active national medicines price monitoring system for retail prices	Yes ☒ No ☐	1980	according to law 108 2011 attached inspection checklist on pharmacies
6.03.03	Regulations exists mandating that retail medicine price information should be publicly accessible	Yes ☒ No ☐	2011	eda.mohealth.gov.eg/services/CAPA committee/ pricing comittee
6.03.03.01	-if yes, please explain how the information is made publically available	eda.mohealth.gov.eg/services/CAPA committee/pricing comittee		
6.03.04	Comments and References	for question 6.03.01 minsterial decree number 373 for year 2009 , 314 year1992, 38 year 1993, 298 year2006,150 year1990 , 313 for year 1991		

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 ☐			2004	survey report of the prices people have to pay for medicines in Egypt
	Basket Of key medicines			Public procurement	Public patient	Private patient		
	Availability (one or both of)	**Mean (%)**	**Orig**		6.04.01.01 100	6.04.01.03 100		
			LPG		6.04.01.02 100	6.04.01.04 100		
		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 2.73		
			LPG	6.04.03.02 0.95	6.04.03.04 0.95	6.04.03.06 1.69		
	Affordability Days' wages of the	**Number of days'**	**Orig**		6.04.04.01	6.04.04.03		

	lowest paid govt worker for standard treatment with co-trimoxazole for a child respiratory infection	**wages**	**LPG**		6.04.04.02 0.3	6.04.04.04 0.5	
6.04.05	Comments and References			for question 6.04.01.01 , 6.04.01.02, 6.04.01.03 , 6.01.01.04 One explanation for high availability in the public sector is that Egypt has an Essential Drug List which corresponds very well with the core list used in the survey. Although a few essential medicines have been added by use of the supplementary list, average availability remains high. Nevertheless, it has to be remembered that our estimate is based on a one point in time investigation for question 6.04.03.01 and 6.04.03.03 As no innovator brand product was found in the governmental sector, the comparison of innovator brands between the sectors becomes impossible and we have compared only the prices of generic equivalents for question 6.04.04.02 and 6.04.04.04 this values are about amoxicillin as ther isn't data about affordability of co-trimoxazole in that survay			

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 ☐	2004	survey report of the prices people have to pay for medicines in egypt
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	data available isn't enough to fill this questions
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 ☐	1975	law 118 for 1975 ministerial decree113 for year 1962
6.06.02	There are duties on imported finished products	Yes ☒ No ☐	1975	law 118 for year 1975 ministerial decree113 for year 1962
6.06.03	VAT (value-added tax) or any other tax is levied on finished pharmaceuticals products	Yes ☒ No ☐	1991	law number 11 for year 1991
6.06.04	There are provisions for tax exceptions or waivers for pharmaceuticals and health products	Yes ☒ No ☐	1991	ministerial decree 314 for year 1992 and law 11 of 1991 ministerial decree number 321 for year 2010 , decree 709 for year 1978 for acdema companies

6.06.05	Please specify categories of pharmaceuticals on which the taxes are applied and describe the exemptions and waivers that exist	taxes are applied to all pharmaceuticals except that stated in the attached law 11 and ministerial decree 314 regarding medicines of chronic diseases and products of acdema companies (which is also duties free) , also all active ingredients tax free but first their companies must apply request to CAPA to release ministerial decree including a list of this materials Exempted like the decree attached(321)		
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 (%)	0.05	1975	law 118for year 1975 look also the attached cost sheet
6.06.09S	VAT on pharmaceutical products (%)	0.05	1991	law number 11 for year 1991 look also the attached cost sheet
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	raghda shehab eldeen abd elateef
7.00.02	Phone number	0020121468362
7.00.03	Email address	dr_raghda87@hotmail.com
7.00.04	Other respondents for filling out this section	dr rasha abo shady the head of procrutment department dr hossam head of general pharmacy inspection dr maha edres head of factories inspection dr salwa zhran head of licening general pharmacy organization

7.01 Public Sector Procurement

Core Questions (click here for help)

			Date	Source
7.01.01	Public sector procurement is:		2011	look the headline of tender condition booklet
7.01.01.01	Decentralized	☐Yes		
7.01.01.02	Centralized and decentralized	☒Yes		
7.01.01.03	Please describe	look flow chart attached illustrating the public procrutment process		
7.01.02	If public sector procurement is wholly or partially centralized, it is under the responsibility of a procurement agency which is:		2011	dr rasha abo shady the head of procrutmen department

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 ☐	2010	elgomhoria national journal
7.01.04	Public sector tender awards are publicly available	Yes ☒ No ☐	2011	eda.mohealth.gov.eg/Announcement
7.01.05	Procurement is based on prequalification of suppliers	Yes ☒ No ☐	2007	prequalification criteria by dr rasha aboshady 2011
7.01.05.01	If yes, please describe how it works	A team from procrutment department make inspection visit in 2007 to different drug suppliers according to this prequalification criteria then fed the data in a database in IT of ministery of health , any suppliers must fill the requiered criteria in this database before application to a procrutment process and any changes or addition regarding their data fed it in this database		
7.01.06	Comments and References	for question 7.01.01public procurement process is centeralized for hospitals , health units and Medical Convoys of ministery of health and decenteralized because national procrutment agency hasn't the responsibility of procrutment process of univeristy hospitals which follow ministery of heigher education		
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 ☐	1998	The law of tenders and auctions 89 for

				year1998 2011
7.01.08S	Are there legal provisions giving priority in public procurement to goods produced by local manufacturers?	Yes ☒ No ☐	1998	The law of tenders and auctions 89 for year1998 2011
7.01.09S	The key functions of the procurement unit and those of the tender committee are clearly separated	Yes ☐ No ☒	1998	The law of tenders and auctions 89 for year1998 2011
7.01.10S	A process exists to ensure the quality of products procured	Yes ☒ No ☐	2011	tender condition booklet and attached copy of record of inspection of pulled sampels
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-qualification of suppliers	Yes ☒ No ☐		
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	Yes ☒ No ☐	2010	attached copy of

	quality testing are available			record of inspection of pulled sampels
7.01.12S	Which of the following tender methods are used in public sector procurement:		2011	dr rasha abo shady the head of procrutmen department
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	7.01.11s pulled sampels of procured drugs by inspection department is known by suppliers		

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 ☐		
7.02.02	Number of public warehouses in the secondary tier of public distribution (State/Regional/Provincial)	194	2011	attached statistical record january
7.02.03	There are national guidelines on Good Distribution Practices (GDP)	Yes ☒ No ☐	2009	national GDP for pharmaceutical products 2011
7.02.04	There is a licensing authority that	Yes ☒ No ☐	2009	Ministerial Decree

	issues GDP licenses			number 380 and 25 2011
7.02.04.01	If a licensing authority exists, does it accredit public distribution facilities?	Yes ☐ No ☒		
7.02.05	List of GDP certified warehouses in the public sector exists	Yes ☐ No ☒		
7.02.06	List of GDP certified distributors in the public sector exists	Yes ☐ No ☒		
7.02.07	Comments and References	for question 7.02.04.01 all the legal provisions regarding accrediting and licinening the distribution facilities are only applicable to the private sector and haven't direct authority on public ones , only send recommendations to them to take this minsterial decrees 380 and 25 into considerations even upon inspection there is acheck list attached for inspection according to GSP only for question 7.02.02 that is the only number reported because no reportes are received from Red Sea Governorate,el oksor governerate,bany swef governerate andSouth Sinai		

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			
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 ☐		
7.02.12S	The Public Central Medical Store is GDP certified by a licensing authority	Yes ☐ No ☐		
7.02.13S	The Public Central Medical Store is ISO certified	Yes ☐ No ☐		
7.02.14S	The second tier public warehouses are GDP certified by a licensing authority	Yes ☐ No ☐		
7.02.15S	The second tier public warehouses are ISO certified	Yes ☐ No ☐		
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 ☐	2009	ministerial decree number 380 for year 2009 and pharmacy law 127 for year 1955 code 40-

				45 2011
7.03.02	Legal provisions exist for licensing distributors in the private sector	Yes ☒ No ☐	2009	ministerial decree number 380 for year 2009 and pharmacy law 127 for year 1955 code 40-45 2011
7.03.03	List of GDP certified wholesalers in the private sector exists	Yes ☒ No ☐	2011	national distributers list
7.03.04	List of GDP certified distributors in the private sector exists	Yes ☒ No ☐	2011	national distributers list
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	Ghada Mohamed Ahmed
8.00.02	Phone number	202 0148522130
8.00.03	Email address	dr_ghada13@yahoo.com
8.00.04	Other respondents for filling out this section	dr/ Rasha Aboushady dr/ Hadir Mamdouh dr/ Osama Ramadan dr/ Nira Niazi

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 ☐	2006	WHO level I
8.01.01.01	If yes, number of medicines on the EML (no. of INN)	500		
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	Yes ☒ No ☐	2010 2011	MOH

	update of STGs in the "year" field			
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 ☐	2008	WHO level I
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 ☐	2006	WHO level I
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 ☐	2010	MOH-Egypt 2011
8.01.06	% of public health facilities with copy of EML (mean)- Survey data	41.2	2008	WHO essential drugs & medicines policy
8.01.07	% of public health facilities with copy of STGs (mean)- Survey data	26.5	2008	WHO essential drugs & medicines policy
8.01.08	A public or independently funded national medicines information centre provides information on medicines to prescribers, dispensers and consumers	Yes ☐ No ☒	2007	WHO level I
8.01.09	Public education campaigns on rational medicine use topics have been conducted in the previous two years	Yes ☐ No ☐		unavailable
8.01.10	A survey on rational medicine use has been conducted in the previous	Yes ☒ No ☐	2010	Central Administer ation of

	two years			Phamaceutical Affairs (CAPA)-EPVC-MOH 2011
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 ☐	2007	WHO level I
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" field	Yes ☐ No ☒	2007	WHO level I
8.01.13	Comments and References	8.01.01.02 , 8.01.01.03 , 8.01.01.04: The reference is Central Administeration of Pharmaceutical Affairs (CAPA) - procurement department the responsible person is dr. Rasha Aboshady 8.01.01.04: There is a mechanism to align the EML with the (STG) especially in oncology medicines. 8.01.11 Yes there is committee on facilities level to monitor drugs utilization , following of clinical guidelines begining in 2002 and still until now.		

Supplementary questions (click here for help)

			Year	Source
8.01.14S	The Essential Medicines List (EML) includes formulations specific for children	Yes ☒ No ☐	2011	CAPA-MOH
8.01.15S	There are explicitly documented criteria for the selection of medicines in the EML	Yes ☐ No ☒	2011	CAPA-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	WHO level I

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 ☒	2007	WHO level I
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 ☐	2008	MOH-USAID-Egypt
8.01.19S	A national reference laboratory/or any other institution has responsibility for coordinating epidemiological surveillance of antimicrobial resistance	Yes ☐ No ☒	2007	WHO level I
8.01.20S	Comments and References	8.01.14S , 8.01.15S , 8.01.16S , 8.01.16.01S: The reference is Central Administeration of Pharmaceutical Affairs (CAPA) - procurement department the responsible person is dr. Rasha Aboshady 8.01.16S : Attached Reference from procurement departement at CAPA - MOH 8.01.16.01s : Attached Reference from CAPA - MOH 8.01.18S URL: http://www.mohp.gov.eg/programs/InfectFight/DocLib/part33.pdf comment: usaid helps with the Egyptian government to improving the country's infectious diseases surveillance system through the Infection Control Program (ICP)		

8.02 Prescribing

Core Questions (click here for help)

			Year	Source
8.02.01	Legal provisions exist to govern the	Yes ☒ No ☐	2011	Egyptian

	licensing and prescribing practices of prescriber			Medical Syndicate
8.02.02	Legal provisions exist to restrict dispensing by prescribers	Yes ☒ No ☐	2011	Egyptian Medical Syndicate
8.02.03	Do prescribers in the private sector dispense medicines?	Yes ☒ No ☐	2007 2011	WHO level I
8.02.04	Regulations require hospitals to organize/develop Drug and Therapeutics Committees (DTCs)	Yes ☒ No ☐	2007 2011	WHO level I
8.02.05	Do more than half of referral hospitals have a DTC?	Yes ☐ No ☐ Unknown ☒	2007 2011	WHO level I
8.02.06	Do more than half of general hospitals have a DTC?	Yes ☒ No ☐ Unknown ☐	2007 2011	WHO level I
8.02.07	Do more than half of regions/provinces have a DTC?	Yes ☒ No ☐ Unknown ☒	2007 2011	WHO level I
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 ☒	2007 2011	WHO level I

8.02.10	Mandatory continuing education that includes pharmaceutical issues is required for nurses	Yes ☐ No ☒		nursing syndicate
8.02.11	Mandatory continuing education that includes pharmaceutical issues is required for paramedical staff	Yes ☐ No ☒	2007	WHO level I 2011
8.02.12	Prescribing by INN name is obligatory in:		2007	WHO level I
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)	2.3	2008	MOH - WHO
8.02.14	% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)	88.47	2008	MOH - WHO 2011
8.02.15	% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)	37.5	2008	MOH - WHO 2011
8.02.16	% of patients in outpatient public health care facilities receiving antibiotics (mean)	49.8	2008	MOH - WHO
8.02.17	% of patients in outpatient public health care facilities receiving injections (mean)	13.2	2008	MOH - WHO 2011
8.02.18	% of prescribed drugs dispensed to patients (mean)	91.2	2008	MOH - WHO 2011
8.02.19	% of medicines adequately labeled in public health facilities (mean)	45.2	2008	MOH - WHO 2011
8.02.20	Comments and References	References: World Health Organization - Department of Essential Drugs and Medicines Policy - Ministry of Health -(Egyptian National		

		Drug Policy Survey) - Softcopy attached		
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 ☐	2011	Egyptian Medical Syndicate
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) (%)	85.1	2008	MOH - WHO 2011
8.02.24S	Comments and References	8.02.23S : data according to (Egyptian National Drug Policy Survey)- softcopy attached.		
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 ☐	2011	CAPA - MOH
8.03.02	The basic pharmacist training curriculum includes components on:			
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 ☒	2007	WHO level I
8.03.04	Generic substitution at the point of dispensing in public sector facilities is allowed	Yes ☒ No ☐	2007 2011	WHO level I
8.03.05	Generic substitution at the point of dispensing in private sector facilities is allowed	Yes ☒ No ☐	2007 2011	WHO level I
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 2011	WHO level I
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 2011	WHO level I
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 ☐	2011 2011	Egyptian Pharmacist Syndicate
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	WHO level I
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	8.03.09S Egyptian Pharmacist Syndicate URL: egypharmsynd.org/files/h6.jpg - hardcopy attached.

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	
9.00.02	Phone number	
9.00.03	Email address	
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?			
9.01.02	Adults with acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)			
9.01.03	Adults with acute conditions not taking all medicines because they cannot afford them (%)			
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 (%)			
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 (%)			

9.01.06	Adults with chronic conditions taking all medicines prescribed by an authorized prescriber (%)			
9.01.07	Adults (from poor households) with chronic conditions not taking all medicines because they cannot afford them (%)			
9.01.08	Adults (from poor households) with chronic conditions who usually take all medicines prescribed by an authorized prescriber (%)			
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 (%)			
9.01.10	Percentage of people who obtained the medicines prescribed in the 15 days before the interview (%)			
9.01.11	People who obtained prescribed medicines for free in the 15 days before the interview (%)			
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 (%)			
9.01.14S	Adults with chronic conditions not taking all medicines because they cannot afford them (%)			
9.01.15S	Adults with chronic conditions not taking all medicines because the medicines were not available (%)			
9.01.16S	Children with acute conditions taking all medicines prescribed by			

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