Ghana

PHARMACEUTICAL COUNTRY PROFILE
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Foreword

The 2011 Pharmaceutical Country Profile for Ghana 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 Ghana. 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 behalf of the Ministry of Ghana, I wish to express my appreciation to Mr. James Ohemebg Kyei, George Hedidor, Samuel Kwakwah, Martha Gyansa-Lutterodt, Saviour Yevutsey, Akua Amartey, Samual Boateng and Seth Seaneke for their contributions to the process of data collection and the development of this profile.

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

Name: HON JOSEPH YIELEH CHIREH MP

Function in the Ministry of Health: MINISTER OF HEALTH

Date: 3RD FEBRUARY 2012

Signature...
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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 Ghana. 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/cooperation/cooperation_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. The compiled data comes from international sources (e.g. the World Health Statistics\textsuperscript{1,2}), surveys conducted in the previous years and country level information collected in 2011.

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 Ghana was Mr. James Ohemeng Kyei. More information about the Pharmaceutical Country Profile is available on WHO web site at:


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. Comments, suggestions or corrections may be sent to:
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jamesohemengkyei@yahoo.com
+233244825454
Section 1 - Health and Demographic Data

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

1.1 Demographics and Socioeconomic Indicators

The total population of Ghana in 2009 was 23,837,000 with an annual population growth rate of 2.1%. The annual GDP growth rate in 2009 is 4.7%. The GDP per capita was US$ 1,139.823.

The proportion of the population under 15 years of age is 39%, and over 60 years of age is 6%. The urban population currently stands at 50% of the total population4. The fertility rate in Ghana is 3.9 births per woman3. There is 30% of the population living with less than $1.25/day (international PPP). The income share held by the lowest 20% of the population is 5.2% (as a % of national income)5. The adult literacy rate for the population over 15 years is 65%4.

1.2 Mortality and Causes of Death

The life expectancy at birth is 60 and 64 years for men and women respectively4. The infant mortality rate (i.e. children under 1 year) is 47/1,000 live births. For children under the age of 5, the mortality rate is 69/1,000 live births6. The maternal mortality rate is 560/100,000 live births7.

The adult mortality rate for both sexes between 15 and 60 years is 273 / 1,000 population, while the neonatal mortality rate is 30 / 1,000 live births4. The age-standardised mortality rate for non-communicable diseases is 699 / 100,0008, 343 / 100,000 for cardiovascular diseases and 127 / 100,000 for cancer9. The mortality rate for HIV/AIDS is 89 / 100,000 and 44 / 100,000 for tuberculosis2. The mortality rate for Malaria is 109 / 100,00010.
Table 1: The top 10 diseases causing mortality in Ghana\textsuperscript{11}

<table>
<thead>
<tr>
<th>Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Malaria</td>
</tr>
<tr>
<td>2 HIV/AIDS related conditions</td>
</tr>
<tr>
<td>3 Anaemia</td>
</tr>
<tr>
<td>4 Cerebrovascular accidents</td>
</tr>
<tr>
<td>5 Pneumonia</td>
</tr>
<tr>
<td>6 Septicaemia</td>
</tr>
<tr>
<td>7 Hypertension</td>
</tr>
<tr>
<td>8 Cardiac diseases</td>
</tr>
<tr>
<td>9 Meningitis</td>
</tr>
<tr>
<td>10 Diarrhoeal diseases</td>
</tr>
</tbody>
</table>

The source of the top 10 diseases causing mortality in Ghana is The Health Sector in Ghana, Facts and Figures, 2009.

Table 2: The top 10 diseases causing morbidity in Ghana\textsuperscript{11}

<table>
<thead>
<tr>
<th>Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Malaria</td>
</tr>
<tr>
<td>2 Upper respiratory tract infections</td>
</tr>
<tr>
<td>3 Diarrhoeal diseases</td>
</tr>
<tr>
<td>4 Skin diseases</td>
</tr>
<tr>
<td>5 Hypertension</td>
</tr>
<tr>
<td>6 Home occupational injuries</td>
</tr>
<tr>
<td>7 Acute eye infections</td>
</tr>
<tr>
<td>8 Pregnancy and related complications</td>
</tr>
<tr>
<td>9 Rheumatic and joint diseases</td>
</tr>
<tr>
<td>10 Anaemia</td>
</tr>
</tbody>
</table>

The source of the top 10 diseases causing morbidity in Ghana is The Health Sector in Ghana, Facts and Figures, 2009.
Section 2 - Health Services

This section provides information regarding health expenditures and human resources for health in Ghana. 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 Ghana, the total annual expenditure on health (THE) in 2008 was 1,375.94 million Ghanaian Cedi (US$ 1,298.05 million). The total annual health expenditure was 7.79% of the GDP. The total annual expenditure on health per capita was 58.92 Ghanaian Cedi (US$ 55.59).

The general government\(^1\) health expenditure (GGHE) in 2008, as reflected in the national health accounts (NHA) was 683.78 million Ghanaian Cedi (US$ 645.08 million). That is, 49.7% of the total expenditure on health, with a total annual per capita public expenditure on health of 29.28 Ghanaian Cedi (US$ 27.63). The government annual expenditure on health represents 7.59 % of the total government budget. Private health expenditure covers the remaining 50.3% of the total health expenditure\(^2\).

Of the total population, 66.4% is covered by a public health service, public health insurance or social insurance, or other sickness funds\(^3\).

Social security expenditure makes up 29.7 % of government expenditure on health\(^2\). The annual growth rate of total pharmaceutical market value is 7%\(^4\).

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\(^1\) According to the NHA definition, by "government expenditure" means all expenditure from public sources, like central government, local government, public insurance funds and parastatal companies.
Private out-of-pocket expenditure as % of private health expenditure is 79.19%. Premiums for private prepaid health plans are 5.85 % of total private health expenditure\textsuperscript{12}.

2.2 Health Personnel and Infrastructure

The health workforce is described in the table below and in Figure 1 and 2. There are 2,900\textsuperscript{15} (1.22/10,000) licensed pharmacists, of whom 372\textsuperscript{16} (0.16/10,000) work in the public sector. There are 1,126\textsuperscript{17} (0.47/10,000) pharmaceutical technicians and assistants (in all sectors). There are approximately 2.5 as many pharmacists as pharmacy technicians.

There are 2,587\textsuperscript{4} (1.11/10,000) physicians and 22,834\textsuperscript{9} (9.78/10,000) nursing and midwifery personnel in Ghana. The ratio of doctors to pharmacists is 0.89 and the ratio of doctors to nurses and midwifery personnel is 0.11. As of 2011 there is a strategic plan for pharmaceutical human resource development, in draft\textsuperscript{18}.

Table 3: Human resources for health in Ghana

<table>
<thead>
<tr>
<th>Human Resource</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Licensed pharmacists (all sectors)</td>
<td>2900\textsuperscript{15} (1.22/10,000)</td>
</tr>
<tr>
<td>Pharmacists in the public sector</td>
<td>372\textsuperscript{16} (0.16/10,000)</td>
</tr>
<tr>
<td>Pharmaceutical technicians and assistants (all sectors)</td>
<td>1,126\textsuperscript{17} (0.47/10,000)</td>
</tr>
<tr>
<td>Physicians (all sectors)</td>
<td>2,587\textsuperscript{4} (1.11/10,000)</td>
</tr>
<tr>
<td>Nursing and midwifery personnel (all sectors)</td>
<td>22,834\textsuperscript{9} (9.78/10,000)</td>
</tr>
</tbody>
</table>
The health facility structure is described in Table 4. There are 364 hospitals\textsuperscript{11} and 21,453 hospital beds in Ghana\textsuperscript{9}. There are 2,639 primary health care units\textsuperscript{11} and centres and 2,400 licensed pharmacies\textsuperscript{15}. The total number of pharmacists who graduated (as a first degree) in the past 2 years is 265. Accreditation requirements for pharmacy schools are in place and the pharmacy curriculum is regularly reviewed\textsuperscript{15}. 
Table 4: Health centre and hospital statistics

<table>
<thead>
<tr>
<th>Infrastructure</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitals</td>
<td>364\textsuperscript{11}</td>
</tr>
<tr>
<td>Hospital beds</td>
<td>21,4539</td>
</tr>
<tr>
<td>Primary health care units and centres</td>
<td>2639\textsuperscript{11}</td>
</tr>
<tr>
<td>Licensed pharmacies</td>
<td>2400\textsuperscript{15}</td>
</tr>
</tbody>
</table>
Section 3 - Policy Issues

This section addresses the main characteristics of the pharmaceutical policy in Ghana. 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/Jh2283e/). Information about the capacity for manufacturing medicines and the legal provisions governing patents is also provided.

3.1 Policy Framework

In Ghana, a National Health Policy (NHP) exists\textsuperscript{19}. It was last updated in 2005. An official National Medicines Policy document also exists in Ghana. It was updated in 2004\textsuperscript{20}.

A NMP implementation plan also exists which was most recently updated in 2006\textsuperscript{21}. Policies addressing pharmaceuticals exists as detailed in Table 5. Pharmaceutical policy implementation is regularly monitored/assessed by the manager of Ghana National Drugs Programme\textsuperscript{22}.

Table 5: The NMP covers\textsuperscript{20}

<table>
<thead>
<tr>
<th>Aspect of policy</th>
<th>Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection of essential medicines</td>
<td>Yes</td>
</tr>
<tr>
<td>Medicines financing</td>
<td>Yes</td>
</tr>
<tr>
<td>Medicines pricing</td>
<td>No</td>
</tr>
<tr>
<td>Medicines Procurement</td>
<td>Yes</td>
</tr>
<tr>
<td>Medicines Distribution</td>
<td>Yes</td>
</tr>
<tr>
<td>Medicines Regulation</td>
<td>Yes</td>
</tr>
<tr>
<td>Pharmacovigilance</td>
<td>Yes</td>
</tr>
<tr>
<td>Rational use of medicines</td>
<td>Yes</td>
</tr>
<tr>
<td>Human Resource Development</td>
<td>Yes</td>
</tr>
<tr>
<td>Research</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td>-------</td>
</tr>
<tr>
<td>Monitoring and evaluation</td>
<td>Yes</td>
</tr>
<tr>
<td>Traditional Medicine</td>
<td>Yes</td>
</tr>
</tbody>
</table>

There are official written guidelines on medicines donations\textsuperscript{21}.  

\textsuperscript{21}
Section 4 – Medicines Trade and Production

4.1 Intellectual Property Laws and Medicines

Ghana is a member of the World Trade Organization\textsuperscript{23}. Legal provisions for granting patents to manufacturers exist, covering pharmaceuticals. Intellectual Property Rights are managed and enforced by Patent Office, Registrar General's Department\textsuperscript{24}.

National Legislation has been modified to implement the TRIPS Agreement and laws containing TRIPS-specific flexibilities and safeguards are awaiting parliamentary approval\textsuperscript{25}. Ghana is not eligible for the transitional period to 2016\textsuperscript{26}. There are no legal provisions for data exclusivity for pharmaceuticals, patent extension or patent status and marketing authorization\textsuperscript{26}.

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

<table>
<thead>
<tr>
<th>Flexibility and safeguards</th>
<th>Included</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compulsory licensing provisions that can be applied for reasons of public health</td>
<td>No</td>
</tr>
<tr>
<td>Bolar exceptions\textsuperscript{ii}</td>
<td>No</td>
</tr>
<tr>
<td>Parallel importing provisions</td>
<td>No</td>
</tr>
</tbody>
</table>

\textsuperscript{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. \textit{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")

\textit{[In: WTO OMC Fact sheet: TRIPS and pharmaceutical patents, can be found on line at: http://www.wto.org/english/tratop_e/trips_e/tripfactsheet_pharma_2006_e.pdf]}
4.2 Manufacturing

In 2005 there were 34 licensed pharmaceutical manufacturers in Ghana\textsuperscript{27}, all of which are Good Manufacturing Practice (GMP) certified\textsuperscript{26}. Manufacturing capabilities are presented in Table 5 below.

Table 5: Ghana manufacturing capabilities\textsuperscript{21}

<table>
<thead>
<tr>
<th>Manufacturing capabilities</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and Development for discovering new active substances</td>
<td>No</td>
</tr>
<tr>
<td>Production of pharmaceutical starting materials (APIs)</td>
<td>Yes</td>
</tr>
<tr>
<td>The production of formulations from pharmaceutical starting material</td>
<td>Yes</td>
</tr>
<tr>
<td>The repackaging of finished dosage forms</td>
<td>Yes</td>
</tr>
</tbody>
</table>

In 2005, domestic manufacturers held 37\% of the market share by value produced. The percentage of market share by volume produced by domestic manufacturers is 20\%\textsuperscript{27}. There are no multinational pharmaceutical companies currently manufacturing medicines locally\textsuperscript{26}. 
Section 5 – Medicines Regulation

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

5.1 Regulatory Framework

There are legal provisions establishing the powers and responsibilities of the Medicines Regulatory Authority (MRA). In Ghana the MRA is the Food and Drugs Board (FDB)\textsuperscript{28}. The MRA is a part of the MoH with a number of functions outlined in Table 6\textsuperscript{29}. The MRA has its own website, for which the URL address is \url{http://www.fdbghana.gov.gh}.

Table 6: Functions of the national MRA\textsuperscript{29}

<table>
<thead>
<tr>
<th>Function</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marketing authorisation / registration</td>
<td></td>
</tr>
<tr>
<td>Inspection</td>
<td></td>
</tr>
<tr>
<td>Import control</td>
<td></td>
</tr>
<tr>
<td>Licensing</td>
<td></td>
</tr>
<tr>
<td>Market control</td>
<td></td>
</tr>
<tr>
<td>Quality control</td>
<td></td>
</tr>
<tr>
<td>Medicines advertising and promotion</td>
<td></td>
</tr>
<tr>
<td>Clinical trials control</td>
<td></td>
</tr>
<tr>
<td>Pharmacovigilance</td>
<td></td>
</tr>
</tbody>
</table>

As of 24/06/2011, there were 316 permanent staff working for the FDB. The FDB receives external technical assistance with proficiency testing in USP training, participation in WHO prequalification, dossier evaluation and inspections. The MRA is involved in harmonization/collaboration initiatives such as West African Health Organization harmonization of registration and inspection requirements\textsuperscript{21, 30}. An assessment of the medicines regulatory system has not been conducted in the last five years\textsuperscript{29}. Funding for the MRA is provided through the regular
government budget, as well as through additional sources, including funds from fees for services provided\textsuperscript{21}, from the United States Pharmacopeial Convention (USP) to control the quality of antimalarials and the Global Fund\textsuperscript{29}.

The Regulatory Authority does not retain revenues derived from regulatory activities. Revenue derived goes towards the consolidated funds of government. This body utilizes a computerized information management system to store and retrieve information on processes that include registrations, inspection etc\textsuperscript{29}.

5.2 Marketing Authorization (Registration)

In Ghana, legal provisions require marketing authorization (registration) for all pharmaceutical products on the market\textsuperscript{21} and no mechanisms for exceptions/waivers exist. Information from the prequalification programme managed by WHO is used for product registration. Mutual recognition mechanisms are in place for recognition of registration done by other countries. Explicit and publicly available criteria exist for assessing applications for marketing authorization of pharmaceutical products\textsuperscript{29}. In 2011, there were 2,488 pharmaceutical products registered in Ghana\textsuperscript{31}. There are legal provisions requiring the MRA to make the list of registered pharmaceutical products publicly available and update it regularly\textsuperscript{32}. This register is updated every 2 months. The updated list can be accessed through http://www.fdbghana.gov.gh/images/pdf/DrugReg_March21.pdf. Medicines are always registered by their INN (International Non-proprietary Names) or Brand name + INN\textsuperscript{21}. Legal provisions require a fee to be paid for Medicines Market Authorization (registration) based on applications\textsuperscript{29}.

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 not required to be published\textsuperscript{29}. However, legal provisions requiring the establishment of an expert committee involved in the Marketing Authorization process are in place.
Possession of a Certificate for Pharmaceutical Products (that accords with the WHO Certification scheme) is required as part of the Marketing Authorization application\textsuperscript{21}. 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 containin a New Chemical Entity (NCE) is US$ 4,500, while this fee for generic pharmaceutical products is US$ 3,000.

The time limit imposed for the assessment of all Marketing Authorization applications is 4.5 months. The average length of time for assessment is 180 days for patented products and 90 days for generics\textsuperscript{29}.

5.3 Regulatory Inspection

In Ghana, legal provisions exist allowing for appointment of government pharmaceutical inspectors\textsuperscript{33}. However, legal provisions do not 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 private facilities\textsuperscript{21, 33}. Where inspections are legal requirements, these are not the same for public and private facilities\textsuperscript{29}. Inspections are carried out on a number of entities, outlined in Table 7.

The Pharmacy Council is legally mandated to inspect pharmacies and drug dispensing outlets. The Food and Drugs Board inspects factories, warehouses and carries out post-market surveillance\textsuperscript{29}.
Table 7: Local entities inspected for GMP compliance\textsuperscript{21}

<table>
<thead>
<tr>
<th>Entity</th>
<th>Inspection</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local manufacturers</td>
<td>Yes</td>
<td>At least once a year</td>
</tr>
<tr>
<td>Private wholesalers</td>
<td>Yes</td>
<td>At least once a year</td>
</tr>
<tr>
<td>Retail distributors</td>
<td>Yes</td>
<td>At least once a year</td>
</tr>
<tr>
<td>Public pharmacies and stores</td>
<td>Yes</td>
<td>At least once a year</td>
</tr>
<tr>
<td>Pharmacies and dispensing points if health facilities</td>
<td>Yes</td>
<td>At least once a year</td>
</tr>
</tbody>
</table>

5.4 Import Control

Legal provisions exist requiring authorization to import medicines. Laws exist that allow the sampling of imported products for testing. Legal provisions exist requiring importation of medicines through authorized ports of entry. Regulations or laws exist to allow for inspection of imported pharmaceutical products at authorized ports of entry. The Food and Drugs Board is responsible for import control as part of its mandate\textsuperscript{29}.

5.5 Licensing

In Ghana, legal provisions exist requiring manufacturers to be licensed\textsuperscript{21}. Legal provisions exist requiring manufacturers (both domestic and international) to comply with Good Manufacturing Practices (GMP)\textsuperscript{29}. Good Manufacturing Practices are published by the government\textsuperscript{32}.

Legal provisions exist requiring importers, wholesalers and distributors to be licensed\textsuperscript{21}. Legal provisions exist requiring wholesalers and distributors to comply with Good Distributing Practices\textsuperscript{29}. Good Distribution Practices are published by the government\textsuperscript{34}.
Table 8: Legal provisions pertaining to licensing

<table>
<thead>
<tr>
<th>Entity requiring licensing</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Importers</td>
<td>Yes</td>
</tr>
<tr>
<td>Wholesalers</td>
<td>Yes</td>
</tr>
<tr>
<td>Distributors</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Legal provisions exist requiring pharmacists to be registered. Legal provisions exist requiring private and public pharmacies to be licensed\(^{33}\), however the Pharmacy Council does not apply this rule to public facilities\(^{29}\). National Good Pharmacy Practice Guidelines are published by the government\(^{35}\). By law, a list of all licensed pharmaceutical facilities is required to be published\(^{34}\).

### 5.6 Market Control and Quality Control

In Ghana, a laboratory exists in Ghana for Quality Control testing and is a functional part of the MRA. The regulatory authority does not contract services elsewhere. Medicines are tested for a number of reasons, summarised in Table 9.

Table 9: Reason for medicines testing

<table>
<thead>
<tr>
<th>Medicines tested:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>For quality monitoring in the public sector(^{\text{iii}})</td>
<td>Yes</td>
</tr>
<tr>
<td>For quality monitoring in the private sector(^{\text{iv}})</td>
<td>Yes</td>
</tr>
<tr>
<td>When there are complaints or problem reports</td>
<td>Yes</td>
</tr>
<tr>
<td>For product registration</td>
<td>Yes</td>
</tr>
<tr>
<td>For public procurement prequalification</td>
<td>No</td>
</tr>
</tbody>
</table>

Samples are collected by government inspectors for undertaking post-marketing surveillance testing\(^{21}\). In the past 2 years, 2,525 samples were taken for quality

\(^{\text{iii}}\) Routine sampling in pharmacy stores and health facilities

\(^{\text{iv}}\) Routine sampling in retail outlets
control testing. Of the samples tested 142 (5.6%) failed to meet the quality standards\textsuperscript{29}. The results are not publicly available\textsuperscript{32}.

5.7 Medicines Advertising and Promotion

In Ghana, legal provisions exist to control the promotion and/or advertising of prescription medicines. The Food and Drugs Board 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. Guidelines and Regulations exist for advertising and promotion of non-prescription medicines\textsuperscript{21}. There is national code of conduct concerning advertising and promotion of medicines by marketing authorization holders\textsuperscript{36}.

The code of conduct applies to both domestic manufacturers and multinational manufacturers, for which adherence is compulsory. The code contains a formal process for complaints and sanctions, although a list of the complaints and sanctions for the last two years is not publicly available\textsuperscript{29}.

5.8 Clinical Trials

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

Legal provisions exist for GMP compliance of investigational products. Sponsor investigators are not legally required to comply with Good Clinical Practices (GCP). Legal provisions do not permit the inspection of facilities where clinical trials are performed\textsuperscript{29}. 

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5.9 Controlled Medicines

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

Table 10: International Conventions to which Ghana is a signatory

<table>
<thead>
<tr>
<th>Convention</th>
<th>Signatory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Convention on Narcotic Drugs, 1961</td>
<td>Yes</td>
</tr>
<tr>
<td>1972 Protocol amending the Single Convention on Narcotic Drugs, 1961</td>
<td>Yes</td>
</tr>
<tr>
<td>Convention on Psychotropic Substances 1971</td>
<td>Yes</td>
</tr>
<tr>
<td>United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Laws exist for the control of narcotic and psychotropic substances, and precursors. The annual consumption of Morphine is 0.071 mg/capita. Figures regarding the annual consumption of certain controlled substances in the country are outlined in Table 11 below.

Table 11: Annual consumption of selected controlled substances in Ghana

<table>
<thead>
<tr>
<th>Controlled substance</th>
<th>Annual consumption (mg/capita)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine</td>
<td>0.071</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>0.000011</td>
</tr>
<tr>
<td>Pethidine</td>
<td>0.036</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>82.1</td>
</tr>
</tbody>
</table>

5.10 Pharmacovigilance

In Ghana, there are no legal provisions in the Medicines Act that provide for pharmacovigilance activities as part of the MRA mandate. Legal provisions also do not exist requiring the Marketing Authorization holder to continuously monitor the safety of their products and report to the MRA. Laws regarding the monitoring
of Adverse Drug Reactions (ADR) do not exist in Ghana\textsuperscript{29}. The Food and Drugs Board (the MRA) also serves as a national pharmacovigilance centre.

The Pharmacovigilance centre has 10 staff members working part-time on pharmacovigilance. The center has not published an analysis report in the previous two years and it does not regularly publish an ADR bulletin. An official standardized form for reporting ADRs is in Ghana and this information pertaining to ADRs is stored in a national ADR database.

In 2010 the ADR database comprised 2079 ADR reports, of which 1721 had been submitted in the previous 2 years. These reports are also sent to the WHO collaborating centre in Uppsala. 897 ADR reports from the database have been forwarded to the WHO collaborating centre in the past 2 years.

There is a national ADR or pharmacovigilence 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 Ghana. A clear communication strategy for routine communication and crises communication exists. ADRs are also monitored in at least one public health program (example TB, HIV, AIDS).

A number of steps are being considered in order to enhance pharmacovigilance system. These include initiating consumer education and reporting, and creating legal provisions for obligatory ADR reporting by industry. There are training courses in pharmacovigilance.

Feedback is provided to reporters, and the ADR database is computerized. Medication errors are not reported. There is a risk management plan presented as part of product dossier submitted for Marketing Authorization. Regulatory decisions were based on local pharmacovigilance data in the last two years.
In the past two years ADR reporting has been done by the following:

Table 12: Professions responsible for reporting ADRs

<table>
<thead>
<tr>
<th>Profession</th>
<th>Report ADRs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctors</td>
<td>Yes</td>
</tr>
<tr>
<td>Nurses</td>
<td>Yes</td>
</tr>
<tr>
<td>Pharmacists</td>
<td>Yes</td>
</tr>
<tr>
<td>Pharmaceutical companies</td>
<td>Yes</td>
</tr>
<tr>
<td>Others</td>
<td>Yes</td>
</tr>
</tbody>
</table>

There is a WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance at the University of Ghana Medical School in Accra. The Centre trains African countries on how to build and strengthen spontaneous adverse drug reaction reporting systems and advocates for improved pharmacovigilance that is integrated into public health programs across Africa, providing technical support to national pharmacovigilance centers.
Section 6 - Medicines Financing

In this section, information is provided on the medicines financing mechanism in Ghana, 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 Ghana, The National Health Insurance Act (NHIA)\textsuperscript{39} made provisions through the National Health Insurance Regulations to provide cost exemptions in certain cases\textsuperscript{40}. Concessions are made for certain groups to receive medicines free of charge (see Table 13). Furthermore, the public health system or social health insurance schemes provides medicines free of charge for particular conditions (see Table 14).

Table 13: Population groups provided with medicines free of charge\textsuperscript{40}

<table>
<thead>
<tr>
<th>Patient group</th>
<th>Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients who cannot afford them</td>
<td>Yes</td>
</tr>
<tr>
<td>Children under 5</td>
<td>Yes</td>
</tr>
<tr>
<td>Pregnant women</td>
<td>Yes</td>
</tr>
<tr>
<td>Elderly persons</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Table 14: Medications provided publicly, at no cost\textsuperscript{40}

<table>
<thead>
<tr>
<th>Conditions</th>
<th>Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>All medicines in the EML</td>
<td>Yes</td>
</tr>
<tr>
<td>Any non-communicable diseases</td>
<td>Yes</td>
</tr>
<tr>
<td>Malaria</td>
<td>Yes</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>Yes</td>
</tr>
<tr>
<td>Sexually transmitted diseases</td>
<td>Yes</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>Yes</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>-----</td>
</tr>
<tr>
<td>Expanded Program on Immunization (EPI) vaccines for children</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Over 95% of disease conditions common in Ghana are covered by the National Health Insurance Scheme (NHIS)\(^v\). 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 outpatients. Private health insurance schemes also provide medicines coverage. They are not required to provide at least partial coverage for medicines that are on the EML\(^{41}\).

### 6.2 Patients Fees and Copayments

Co-payments or fee requirements for consultations are levied at the point of delivery. However, there are no copayments or fee requirements imposed for medicines. Revenue from fees or from the sale of medicines is not used to pay the salaries or supplement the income of public health personnel in the same facility\(^{21}\).

### 6.3 Pricing Regulation for the Private Sector\(^vi\)

In Ghana, there are no legal or regulatory provisions affecting pricing of medicines.

The government does not run an active national medicines price monitoring system for retail prices\(^{21}\). Regulations do not exist mandating that retail medicine price information should be publicly accessible\(^{32}\).

### 6.4 Prices, Availability and Affordability of Key Medicines

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\(^v\) The full NHIS medicines list is updated every 6 months by the National Health Insurance Authority and is available online: [http://www.nhis.gov.gh/_Uploads/dbsAttachedFiles/MedicinesFinal.pdf](http://www.nhis.gov.gh/_Uploads/dbsAttachedFiles/MedicinesFinal.pdf).

\(^vi\) This section does not include information pertaining to the non-profit voluntary sector.
6.5 Price Components and Affordability

There is no data available on price components and affordability.

6.6 Duties and Taxes on Pharmaceuticals (Market)

Ghana imposes duties on imported active pharmaceutical ingredients (APIs) and on imported finished products. Value-added tax or other taxes are imposed on finished pharmaceutical products\(^4\).
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 Ghana.

7.1 Public Sector Procurement

Public sector procurement in Ghana is both centralized and decentralized.

The public sector procurement is centralized under the responsibility of a procurement agency which is a part of the MoH\textsuperscript{42}.

Public sector request for tender documents are publicly available and public sector tender awards are publicly available\textsuperscript{32}. Procurement is based on the prequalification of suppliers\textsuperscript{42}.

There is a written public sector procurement policy, that was approved in 2003. Legal provisions exist that give priority to locally produces goods in public procurement\textsuperscript{42}.

The key functions of the procurement unit and those of the tender committee are clearly separated\textsuperscript{32}. 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 publicly available\textsuperscript{43}.

A list of samples tested during the procurement process and the results of quality testing are available\textsuperscript{32}. The tender methods employed in public sector procurement include national competitive tenders, international competitive tenders, and direct purchasing\textsuperscript{44}. 

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7.2 Public Sector Distribution

The government supply system department in Ghana has a Central Medical Store at National Level\textsuperscript{32}. There are no national guidelines on Good Distribution Practices (GDP). A licensing authority that issues GDP licenses does not exist.

A list of GDP certified wholesalers does not exist in the public sector\textsuperscript{45}.

A number of processes are in place at the Central Medical Store as detailed in Table 15.

Table 15: Processes employed by the Central Medical Store\textsuperscript{42}

<table>
<thead>
<tr>
<th>Process</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Forecasting of order quantities</td>
<td>Yes</td>
</tr>
<tr>
<td>Requisition/Stock orders</td>
<td>Yes</td>
</tr>
<tr>
<td>Preparation of picking/ Packing slips</td>
<td>Yes</td>
</tr>
<tr>
<td>Reports of stock on hand</td>
<td>Yes</td>
</tr>
<tr>
<td>Reports of outstanding order lines</td>
<td>Yes</td>
</tr>
<tr>
<td>Expiry dates management</td>
<td>Yes</td>
</tr>
<tr>
<td>Batch tracking</td>
<td>No</td>
</tr>
<tr>
<td>Reports of products out of stock</td>
<td>Yes</td>
</tr>
</tbody>
</table>

The percentage availability of key medicines at the Central Medical Store (CMS) is 53\%. Routine procedure to track the expiry dates of medicines at the CMS exist. The Public CMS and the second tier public warehouses are not ISO certified. The second tier public warehouses are not GDP certified by a licensing authority\textsuperscript{42}.
7.3 Private Sector Distribution

Legal provisions exist for licensing wholesalers and distributors in the private sector\textsuperscript{39}. As of 2009, a list of GDP certified wholesalers and distributors did not exist in the private sector\textsuperscript{45}. 
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 Ghana.

8.1 National Structures

A National Essential Medicines List (EML) exists. The EML was lastly updated in 2010 and is publicly available. There are currently 334 medicines and 725 formulations on the EML. Selection of medicines for the EML is undertaken through a written process. A mechanism aligning the EML with the Standard Treatment Guidelines (STGs) is in place

There are National Standard Treatment Guidelines (STGs) for the most common illnesses used at all levels of care, including primary care, secondary care and paediatric care. These are produced/endorsed by the MoH in Ghana and were last updated in 2010. Of the public health facilities, 75% have a copy of the EML and 94.4% have a copy of the STGs.

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

A written National Strategy for containing antimicrobial resistance exists, and was last updated in 2009. Ghana’s Essential Medicines List (EML) includes formulations specifically for children. Criteria for the selection of medicines to the EML are explicitly documented. A national medicines formulary does exist.
A funded national intersectoral task force to coordinate the promotion of the appropriate use of antimicrobials and prevention of the spread of infection does not exist\textsuperscript{21}. A national reference laboratory or other institution does not have responsibility for coordinating epidemiological surveillance of antimicrobial resistance\textsuperscript{48}.

### 8.2 Prescribing

Legal provisions exist to govern the licensing and prescribing practices of prescribers\textsuperscript{21}. Furthermore, legal provisions restricting dispensing by prescribers exist\textsuperscript{20}. Prescribers in the private sector do dispense medicines.

There are regulations requiring hospitals to organize/develop Drug and Therapeutics Committees (DTCs). Where there are requirements for DTCs, more than half of referral hospitals and half of regions/provinces have one\textsuperscript{21}.

The training curriculum for doctors and nurses is made up of a number of core components detailed in Table 16. Mandatory continuing education that includes pharmaceutical issues is required for doctors and paramedical staff.

#### Table 16: Core aspects of the medical training curriculum\textsuperscript{21}

<table>
<thead>
<tr>
<th></th>
<th>Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>The concept of EML</td>
<td>Yes</td>
</tr>
<tr>
<td>Use of STGS</td>
<td>Yes</td>
</tr>
<tr>
<td>Pharmacovigilance</td>
<td>No</td>
</tr>
<tr>
<td>Problem based pharmacotherapy</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Prescribing by INN name is obligatory in the public sector\textsuperscript{21} The average number of medicines prescribed per patient contact in public health facilities is 4. Of the medicines prescribed in the outpatient public health care facilities, 87.5% are on the national EML and 59.9% are prescribed by INN name. Of the patients treated in the outpatient public health care facilities, 43.3% received antibiotics and
13.3% received injections. Of medicines in public health facilities, 7.2% were adequately labelled.\textsuperscript{44}

**Table 17: Characteristics of medicines prescribing\textsuperscript{44}**

| % of medicines prescribed in outpatient public health care facilities that are in the national EML (mean) | 87.5 |
| % of medicines in outpatient public health care facilities that are prescribed by INN name (mean) | 59.9 |
| % of patients in outpatient public health care facilities receiving antibiotics (mean) | 43.3 |
| % of patients in outpatient public health care facilities receiving injections (mean) | 13.3 |
| % of medicines adequately labeled in public health facilities (mean) | 7.2 |

A professional association code of conduct which governs the professional behaviour of doctors exists. Similarly, a professional association code of conduct governing the professional behaviour of nurses exists.\textsuperscript{20}

**8.3 Dispensing**

Legal provisions in Ghana exist to govern dispensing practices of pharmaceutical personnel.\textsuperscript{33} The basic pharmacist training curriculum includes a spectrum of components as outlined in Table 18.

**Table 18: Core aspects of the pharmacist training curriculum\textsuperscript{21}**

<table>
<thead>
<tr>
<th>Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>The concept of EML</td>
</tr>
<tr>
<td>Use of STGS</td>
</tr>
<tr>
<td>Drug information</td>
</tr>
<tr>
<td>Clinical pharmacology</td>
</tr>
<tr>
<td>Medicines supply management</td>
</tr>
</tbody>
</table>
Substitution of generic equivalents at the point of dispensing is allowed in public and private sector facilities. Sometimes antibiotics are sold over-the-counter without a prescription. Sometimes injectable medicines are sold over-the-counter without a prescription\textsuperscript{21}.

Mandatory continuing education that includes rational use of medicines is required for pharmacists\textsuperscript{21}. A professional association code of conduct which governs the professional behaviour of pharmacists exists\textsuperscript{32}. In practice, nurses do sometimes prescribe prescription-only medicines at the primary care level in the public sector (even though this may be contrary to regulations)\textsuperscript{21}. 
Section 9 - Household Data/access

This section provides information derived from past household surveys in Ghana regarding actual access to medicines by normal and poor households. In 2008 a WHO Level II Household Survey to measure access to and use of medicines.

In Ghana, of the adult patients with an acute condition in a two-week recall period, 81% took all medicines prescribed by an authorized prescriber. Seven percent of adult patients with an acute condition in a two-week recall period did not take all medicines prescribed to them because they could not afford them.

Of the adult patients from poorhouseholds with an acute condition in a two-week recall period coming, 74% took all medicines prescribed by an authorized prescriber, while 7% did not because they could not afford them.

Of the adult patient population with chronicconditions, 83% took all medicines prescribed by an authorized prescriber. In comparison, 91.9% of adult patients with chronic conditions coming from poorhouseholds took all medicines prescribed by an authorized prescriber. 1.2% of adults from poor households with chronic conditions did not take all medicines prescribed to them because they could not afford them49.

Of the children from poorhouseholds with acute condition in a two-week recall period, 94.4% took all medicines prescribed by an authorized prescriber50.

Table 19: Measures of access to medicine for vulnerable groups50

<table>
<thead>
<tr>
<th>Indicator</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults with acute conditions not taking all medicines because the medicines were not available (%)</td>
<td>84.0</td>
</tr>
<tr>
<td>Adults with chronic conditions not taking all medicines because they cannot afford them (%)</td>
<td>64.1</td>
</tr>
<tr>
<td>Adults with chronic conditions not taking all medicines because the medicines were not available (%)</td>
<td>35.9</td>
</tr>
<tr>
<td>Description</td>
<td>Percentage</td>
</tr>
<tr>
<td>-----------------------------------------------------------------------------</td>
<td>------------</td>
</tr>
<tr>
<td>Children with acute conditions taking all medicines prescribed by an authorized prescriber (%)</td>
<td>94.5</td>
</tr>
<tr>
<td>Children with acute conditions not taking all medicines because they cannot afford them (%)</td>
<td>41.1</td>
</tr>
<tr>
<td>Children with acute conditions not taking all medicines because the medicines were not available (%)</td>
<td>58.1</td>
</tr>
<tr>
<td>Children (from poor households) with acute conditions not taking all medicines because they cannot afford them (%)</td>
<td>35.2</td>
</tr>
</tbody>
</table>
List of key reference documents:

6 World Health Organisation Global Health Statistics, Ghana, Available online: http://apps.who.int/ghodata/?vid=9300&theme=country#
11 The Health Sector in Ghana, Facts and Figures (2009), Available online: www.ghanaihealthservice.org/.../Facts%20and%20Figures%202009.pdf
13 National Health Insurance, Operations Department Data, Available online: http://www.nhis.gov.gh
15 Ghana Pharmacy Council, Personal Communication with Mr. Kwajawh, Officer in charge of data (2011)
16 Assessment of Human Resources for pharmaceutical services in Ghana. Pharmacy Council/MoH (2009)
18 Document in draft, Pharmacy Council, Personal Communication (2011)
19 Ghana National Health Policy "Creating Wealth through Health", Ministry of Health (2007), Available online:
http://www.ghanalegal.com/?id=3&law=193&t=ghanalaws
35 Office of the Chief Pharmacist and Director of Pharmaceutical Services, "Practice Standards for Pharmacists and Pharmaceutical Care Providers", Available online:
http://www.pharmacycouncilghana.org/pdf/PRACTICE%20STANDARDS%20FOR%20PHARMACISTS%20AND%20PHARMACEUTICAL%20CARE%20PROVIDERS.zip


37 International Narcotics Control Board, Available online: http://www.incb.org/

38 WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance, Centre for Tropical Clinical Pharmacol.& Therapeutics, University of Ghana Medical School, Available online: http://apps.who.int/whocc/Detail.aspx?cc_ref=GHA-1&cc_code=gha&cc_subject=pharmaceuticals%20%28including%20essential%20drugs%20and%20medicines%29


41 As reported by Mr. George K. Hedidor on the Ghana Pharmaceutical Country Profile Questionnaire.

42 As reported by Mr Samuel Boateng, Director of Procurement and Supply, Public Procurement Authority, in Ghana Pharmaceutical Country Profile Questionnaire


45 Personal communication with Stores, Supply and Drug Management Unit of the Ministry of Health


48 As reported by Saviour Yevutsey in the Ghana Pharmaceutical Country Profile Questionnaire.

Pharmaceutical Sector Country Profile Questionnaire

GHANA
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.


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/cooperation/cooperation_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 Country Profile Questionnaire. Final Version.
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.

<table>
<thead>
<tr>
<th>7.01.12S</th>
<th>Which of the following tender methods are used in public sector procurement</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.01.12.01S</td>
<td>National competitive tenders</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>7.01.12.02S</td>
<td>International competitive tenders</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>7.01.12.03S</td>
<td>Direct purchasing</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Document</th>
<th>Exact title</th>
<th>Author</th>
<th>Publisher</th>
<th>Year</th>
<th>File name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essential Medicines List</td>
<td>National Medicines List</td>
<td>Ministry of Health</td>
<td>Ministry of Health</td>
<td>2009</td>
<td>EML.doc</td>
</tr>
</tbody>
</table>

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.

![Example of the template profile](image)

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

<table>
<thead>
<tr>
<th>0.01.01</th>
<th>Country (precoded)</th>
<th>Ghana</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01.02</td>
<td>Name coordinator</td>
<td>James Ohemeng Kyei</td>
</tr>
<tr>
<td>0.01.03</td>
<td>Address (Street, City)</td>
<td>Accra</td>
</tr>
<tr>
<td>0.01.04</td>
<td>Phone number</td>
<td>+233244825454</td>
</tr>
<tr>
<td>0.01.05</td>
<td>Email address</td>
<td><a href="mailto:jamesohemengkyei@yahoo.com">jamesohemengkyei@yahoo.com</a></td>
</tr>
<tr>
<td>0.01.06</td>
<td>Web address</td>
<td>none</td>
</tr>
<tr>
<td>0.01.07</td>
<td>Institution</td>
<td>Private Consultant</td>
</tr>
</tbody>
</table>
# Section 1 Health and Demographic data

## 1.00 Respondent Information Section 1

<table>
<thead>
<tr>
<th>Subsection</th>
<th>Description</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.00.01</td>
<td>Name of person responsible for filling out Survey section 1</td>
<td>James Ohemeng Kyei</td>
</tr>
<tr>
<td>1.00.02</td>
<td>Phone number</td>
<td>+233244825454</td>
</tr>
<tr>
<td>1.00.03</td>
<td>Email address</td>
<td><a href="mailto:jamesohemengkyei@yahoo.com">jamesohemengkyei@yahoo.com</a></td>
</tr>
<tr>
<td>1.00.04</td>
<td>Other respondents for filling out this section</td>
<td>George K. Hedidor</td>
</tr>
</tbody>
</table>

## 1.01 Demographic and Socioeconomic Indicators

### Core questions ([click here for help](#))

<table>
<thead>
<tr>
<th>Subsection</th>
<th>Description</th>
<th>Value</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.01.01</td>
<td>Population, total (.000)</td>
<td>23837</td>
<td>2009</td>
<td>WBank Data.</td>
</tr>
<tr>
<td>1.01.02</td>
<td>Population growth rate (Annual %)</td>
<td>2.1</td>
<td>2009</td>
<td>WBank Data</td>
</tr>
<tr>
<td>1.01.03</td>
<td>Total GrossDomesticProduct (GDP) (millions US$)</td>
<td>26170.0</td>
<td>2009</td>
<td>World Bank data</td>
</tr>
<tr>
<td>1.01.04</td>
<td>GDP growth (Annual %)</td>
<td>4.7</td>
<td>2009</td>
<td>World Bank data</td>
</tr>
<tr>
<td>1.01.05C</td>
<td>GDP per capita (US$ current exchange rate)</td>
<td>1097.87</td>
<td></td>
<td>World Bank, 2009</td>
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<tr>
<td>1.01.06</td>
<td>Comments and References</td>
<td>World Bank Data: World development indicators base, Dec 2010</td>
<td></td>
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</tbody>
</table>

### Supplementary questions ([click here for help](#))

<table>
<thead>
<tr>
<th>Subsection</th>
<th>Description</th>
<th>Value</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.01.07S</td>
<td>Population &lt; 15 years (% of total population)</td>
<td>39</td>
<td>2008</td>
<td>WHSurvey</td>
</tr>
<tr>
<td>1.01.08S</td>
<td>Population &gt; 60 years (% of total population)</td>
<td>6</td>
<td>2008</td>
<td>WHSurvey</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire
### 1.01.09S
Urban population (% of total population) 50 2008 WHSurvey

### 1.01.10S
Fertility rate, total (Births per woman) 3.9 2009 World bank data

### 1.01.11S
Population living with less than $1.25/day (international PPP) (%) 29.99 2006 World Bank data

### 1.01.12S
Population living below nationally defined poverty line (%) 28.5 2006 World Bank data

### 1.01.13S
Income share held by lowest 20% of the population (% of national income) 5.20 2006 World Bank data

### 1.01.14S
Adult literacy rate, 15+ years (% of relevant population) 65 2008 WHSurvey

### 1.01.15S
Comments and References World Bank Data: World development indicators base, Dec 2010

---

### 1.02 Mortality and Causes of Death

**Core questions [click here for help]**

<table>
<thead>
<tr>
<th>1.02.01</th>
<th>Life expectancy at birth for men (Years)</th>
<th>60</th>
<th>2008</th>
<th>WHSurvey</th>
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</thead>
<tbody>
<tr>
<td>1.02.02</td>
<td>Life expectancy at birth for women (Years)</td>
<td>64</td>
<td>2008</td>
<td>WHSurvey</td>
</tr>
<tr>
<td>1.02.03</td>
<td>Infant mortality rate, between birth and age 1 (/1,000 live births)</td>
<td>47</td>
<td>2009</td>
<td>WHO</td>
</tr>
<tr>
<td>1.02.04</td>
<td>Under 5 mortality rate (/1,000 live births)</td>
<td>69</td>
<td>2009</td>
<td>WHO</td>
</tr>
<tr>
<td>1.02.05</td>
<td>Maternal mortality ratio (/100,000 live births)</td>
<td>560</td>
<td>2005</td>
<td>WHS-interagency est</td>
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<tr>
<td>1.02.06</td>
<td>Please provide a list of top 10 diseases causing mortality</td>
<td></td>
<td></td>
<td>2009</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
<table>
<thead>
<tr>
<th>Date</th>
<th>Disease Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.02.06.01</td>
<td>Disease 1</td>
<td>Malaria</td>
</tr>
<tr>
<td>1.02.06.02</td>
<td>Disease 2</td>
<td>HIV/AIDS related conditions</td>
</tr>
<tr>
<td>1.02.06.03</td>
<td>Disease 3</td>
<td>Anaemia</td>
</tr>
<tr>
<td>1.02.06.04</td>
<td>Disease 4</td>
<td>Cerebro Vascular Accidents</td>
</tr>
<tr>
<td>1.02.06.05</td>
<td>Disease 5</td>
<td>Pneumonia</td>
</tr>
<tr>
<td>1.02.06.06</td>
<td>Disease 6</td>
<td>Septicaemia</td>
</tr>
<tr>
<td>1.02.06.07</td>
<td>Disease 7</td>
<td>Hypertension</td>
</tr>
<tr>
<td>1.02.06.08</td>
<td>Disease 8</td>
<td>Cardiac diseases</td>
</tr>
<tr>
<td>1.02.06.09</td>
<td>Disease 9</td>
<td>Meningitis</td>
</tr>
<tr>
<td>1.02.06.10</td>
<td>Disease 10</td>
<td>Diarhoeal diseases</td>
</tr>
<tr>
<td>1.02.07</td>
<td>Please provide a list of top 10 diseases causing morbidity</td>
<td></td>
</tr>
</tbody>
</table>

1.02.07.01 | Disease 1 | Malaria |
1.02.07.02 | Disease 2 | Upper respiratory tract infection |
1.02.07.03 | Disease 3 | Diarrhoea diseases |
1.02.07.04 | Disease 4 | Skin diseases |
1.02.07.05 | Disease 5 | Hypertension |
1.02.07.06 | Disease 6 | Home Occupational Injuries |
1.02.07.07 | Disease 7 | Acute eye infections |
1.02.07.08 | Disease 8 | Pregnancy and related complications |

Pharmaceutical Sector Country Profile Questionnaire.
| 1.02.08 | Comments and References | WHO Global Health Statistics, Ghana(http://apps.who.int/ghodata/?vid=9300&theme=country#) The Health Sector in Ghana, Facts and Figures,2009 www.ghanaregionalhealthservice.org/.../Facts%20and%20Figures%202009.pdf |
| 1.02.09S | Adult mortality rate for both sexes between 15 and 60 years (/1,000 population) | 273 | 2008 | WHSurvey |
| 1.02.10S | Neonatal mortality rate (/1,000 live births) | 30 | 2008 | WHSurvey |
| 1.02.11S | Age-standardized mortality rate by non-communicable diseases (/100,000 population) | 699 | 2004 | WHSurvey |
| 1.02.12S | Age-standardized mortality rate by cardiovascular diseases (/100,000 population) | 343 | 2009 | WHSurvey |
| 1.02.13S | Age-standardized mortality rate by cancer (/100,000 population) | 127 | 2009 | WHSurvey |
| 1.02.14S | Mortality rate for HIV/AIDS (/100,000 population) | 89 | 2009 | WHStats 2009 |
| 1.02.15S | Mortality rate for tuberculosis (/100,000 population) | 44 | 2008 | WHSurvey |
| 1.02.16S | Mortality rate for Malaria (/100,000 population) | 109 | 2006 | WHSurvey |
| 1.02.17S | Comments and References | WHStats,2009 (http://www.who.int/whosis/en/index.html) |

**Supplementary questions (click here for help)**

Pharmaceutical Sector Country Profile Questionnaire.
### Section 2 Health Services

#### 2.00 Respondent Information Section 2

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.00.01</td>
<td>Name of person responsible for filling out this section of the instrument</td>
<td>James Ohemeng Kyei</td>
</tr>
<tr>
<td>2.00.02</td>
<td>Phone number</td>
<td>233244825454</td>
</tr>
<tr>
<td>2.00.03</td>
<td>Email address</td>
<td><a href="mailto:jamesohemengkyei@yahoo.com">jamesohemengkyei@yahoo.com</a></td>
</tr>
<tr>
<td>2.00.04</td>
<td>Other respondents for filling out this section</td>
<td>Samuel Kwakwah</td>
</tr>
</tbody>
</table>

#### 2.01 Health Expenditures

**Core questions** ([click here for help](#))

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.01.01</td>
<td>Total annual expenditure on health (millions NCU)</td>
<td>1375.94</td>
<td>2008</td>
</tr>
<tr>
<td>2.01.02</td>
<td>Total annual expenditure on health (millions US$ average exchange rate)</td>
<td>1298.05</td>
<td>2008</td>
</tr>
<tr>
<td>2.01.02C</td>
<td>Total health expenditure as % of Gross Domestic Product</td>
<td>7.79</td>
<td></td>
</tr>
<tr>
<td>2.01.03.01C</td>
<td>Total annual expenditure on health per capita (NCU)</td>
<td>58.92</td>
<td>58.92</td>
</tr>
<tr>
<td>2.01.03.02C</td>
<td>Total annual expenditure on health per capita (US$ average exchange rate)</td>
<td>55.59</td>
<td>55.59</td>
</tr>
<tr>
<td>2.01.04.01</td>
<td>General government annual expenditure on health (millions NCU)</td>
<td>683.78</td>
<td>2008</td>
</tr>
<tr>
<td>2.01.04.02</td>
<td>General government annual expenditure on health (millions US$ average exchange rate)</td>
<td>645.08</td>
<td>2008</td>
</tr>
<tr>
<td>2.01.05</td>
<td>Government annual expenditure on health as percentage of total government budget (% of total government budget)</td>
<td>7.59</td>
<td>2008</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Year</td>
<td>Source</td>
</tr>
<tr>
<td>-----------</td>
<td>-----------------------------------------------------------------------------</td>
<td>------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>2.01.06C</td>
<td>Government annual expenditure on health as % of total expenditure on health (%) of total expenditure on health</td>
<td>2008</td>
<td>NHA data</td>
</tr>
<tr>
<td>2.01.07.01C</td>
<td>Annual per capita government expenditure on health (NCU)</td>
<td>2008</td>
<td>NHA data</td>
</tr>
<tr>
<td>2.01.07.02C</td>
<td>Annual per capita government expenditure on health (US$ average exchange rate)</td>
<td>2008</td>
<td>NHA data</td>
</tr>
<tr>
<td>2.01.08C</td>
<td>Private health expenditure as % of total health expenditure (%) of total expenditure on health</td>
<td>2008</td>
<td>NHA data</td>
</tr>
<tr>
<td>2.01.09</td>
<td>Population covered by a public health service or public health insurance or social health insurance, or other sickness funds of total population</td>
<td>2010</td>
<td>National Health Insurance, Operations Department Data</td>
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<tr>
<td>2.01.10</td>
<td>Population covered by private health insurance (%) of total population</td>
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<tr>
<td>2.01.11.01</td>
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<td></td>
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<td>2.01.11.02</td>
<td>Total pharmaceutical expenditure (millions US$ current exchange rate)</td>
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<tr>
<td>2.01.12.01C</td>
<td>Total pharmaceutical expenditure per capita (NCU)</td>
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<td>PREFILL CALC</td>
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<tr>
<td>2.01.12.02C</td>
<td>Total pharmaceutical expenditure per capita (US$ current exchange rate)</td>
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<tr>
<td>2.01.13C</td>
<td>Pharmaceutical expenditure as a % of GDP (%) of GDP</td>
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<td>PREFILL CALC</td>
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<tr>
<td>2.01.14C</td>
<td>Pharmaceutical expenditure as a % of HealthExpenditure (%) of total health expenditure</td>
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<td>PREFILL CALC</td>
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Pharmaceutical Sector Country Profile Questionnaire.
<table>
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<td>2.01.15.01</td>
<td>Total public expenditure on pharmaceuticals (millions NCU)</td>
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<tr>
<td>2.01.15.02</td>
<td>Total public expenditure on pharmaceuticals (millions US$ current exchange rate)</td>
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**Supplementary questions (click for help)**

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<th>Description</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.01.20S</td>
<td><strong>Socialsecurity</strong> expenditure as % of government expenditure on health (% of government expenditure on health)</td>
<td>29.7</td>
<td>2009</td>
</tr>
<tr>
<td>2.01.21S</td>
<td>Market share of generic pharmaceuticals [branded and INN] by value (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.01.22S</td>
<td>Annual growth rate of total pharmaceuticals market value (%)</td>
<td>7</td>
<td>2009</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
### 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) 79.19 2008 NHA data

### 2.01.25S
Premiums for private prepaid health plans as % of total private health expenditure (% of private expenditure on health) 5.85 2008 NHA data

### 2.01.26S
Comments and References
- WHO Gh stats (http://apps.who.int/ghodata/?vid=9300&theme=country)
- NA=figures not available

### 2.02 Health Personnel and Infrastructure

#### Core questions [click for help]

<table>
<thead>
<tr>
<th>Q</th>
<th>Description</th>
<th>Value</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.02.01</td>
<td>Total number of pharmacists licensed/registered to practice in your country</td>
<td>2900</td>
<td>2010</td>
<td>Pharmacy Council, personal communication</td>
</tr>
<tr>
<td>2.02.02C</td>
<td>Pharmacists per 10,000 population</td>
<td>0.23</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.02.03</td>
<td>Total number of pharmacists working in the public sector</td>
<td>372</td>
<td>2009</td>
<td>HR for Pharmaceutical service</td>
</tr>
<tr>
<td>2.02.04</td>
<td>Total number of pharmaceutical technicians and assistants</td>
<td>1126</td>
<td>2008</td>
<td>Global Health Atlas</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
| 2.02.05 | A strategic plan for pharmaceutical human resource development is in place in your country? | Yes  | No  | Pharmacy Council, personal communication, Document in Draft |
| 2.02.06 | Total number of physicians | 2587 | 2008 | WHSurvey |
| 2.02.07C | Physicians per 10,000 pop | 1.11 | | |
| 2.02.08 | Total number of nursing and midwifery personnel | 22834 | 2009 | WHSurvey |
| 2.02.09C | Nurses and midwives per 10,000 pop | 9.78 | | |
| 2.02.10 | Total number of hospitals | 364 | 2008 | The Health sector in Ghana, Facts and Figures 2009 |
| 2.02.11 | Number of hospital beds per 10,000 pop | 9.00 | 2009 | WHSurvey |
| 2.02.12 | Total number of primary health care units and centres | 2639 | 2007 | The Health sector in Ghana, Facts and Figures 2009 |
| 2.02.13 | Total number of licensed pharmacies | 2400 | 2011 | Pharmacy Council |
| 2.02.14 | Comments and References | | | Pharmacy council figures were obtained from communication with officer in charge of data (Mr Kwakwah - 233208111504) Assessment of human resources for pharmaceutical services in Ghana. Pharmacy Council/MoH, Sept 2009. Funded by WHO/EC The Health Sector in Ghana, Facts and Figures,2009 www.ghanathingservice.org/.../Facts%20and%20Figures%202009.pdf |

Pharmaceutical Sector Country Profile Questionnaire.
### Supplementary questions (click here for help)

<table>
<thead>
<tr>
<th>Question</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starting annual salary for a newly registered pharmacist in the public sector (NCU)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total number of pharmacists who graduated (first degree) in the past 2 years in your country</td>
<td>265</td>
<td>2011 Pharmacy Council</td>
</tr>
<tr>
<td>Are there accreditation requirements for pharmacy schools?</td>
<td>Yes</td>
<td>2011 Pharmacy Council</td>
</tr>
<tr>
<td>Is the Pharmacy Curriculum regularly reviewed?</td>
<td>Yes</td>
<td>Pharmacy Council</td>
</tr>
<tr>
<td>Comments and References</td>
<td></td>
<td>Pharmacy council figures were obtained from communication with officer in charge of data (Mr Kwakwah)</td>
</tr>
</tbody>
</table>
### Section 3 Policy issues

#### 3.00 Respondent Information Section 4

<table>
<thead>
<tr>
<th>3.00.01</th>
<th>Name of person responsible for filling out this section of the instrument</th>
<th>Martha Gyansa-Lutterodt</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.00.02</td>
<td>Phone number</td>
<td></td>
</tr>
<tr>
<td>3.00.03</td>
<td>Email address</td>
<td><a href="mailto:mlutterodt3@yahoo.com">mlutterodt3@yahoo.com</a></td>
</tr>
<tr>
<td>3.00.04</td>
<td>Other respondents for filling out this section</td>
<td>Saviour Yevutsey</td>
</tr>
</tbody>
</table>

#### 3.01 Policy Framework

**Core questions** ([click here for help](#))

<table>
<thead>
<tr>
<th>3.01.01</th>
<th>National Health Policy exists. If yes, please write year of the most recent document in the &quot;year&quot; field.</th>
<th>Yes</th>
<th>No</th>
<th>2007</th>
<th>National Health Policy, MoH 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.01.02</td>
<td>National Health Policy Implementation plan exists. If yes, please write the year of the most recent document in the &quot;year&quot;</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.03</td>
<td>Please provide comments on the Health policy and its implementation plan</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.04</td>
<td>National Medicines Policy official document exists. If yes, please write the year of the most recent document in the &quot;year&quot; field.</td>
<td>Yes</td>
<td>No</td>
<td>2004</td>
<td>WHO level 1 Ghana National Drug Policy 2004</td>
</tr>
<tr>
<td>3.01.05</td>
<td>Group of policies addressing pharmaceuticals exist.</td>
<td>Yes</td>
<td>No</td>
<td>2004</td>
<td>Ghana National Drug Policy</td>
</tr>
<tr>
<td>3.01.06</td>
<td>National Medicines Policy covers the</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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</table>

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Pharmaceutical Sector Country Profile Questionnaire
following components: Yes

<table>
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<th>Code</th>
<th>Description</th>
<th>Yes</th>
<th>No</th>
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</thead>
<tbody>
<tr>
<td>3.01.06.01</td>
<td>Selection of Essential Medicines</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>3.01.06.02</td>
<td>Medicines Financing</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>3.01.06.03</td>
<td>Medicines Pricing</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>3.01.06.04</td>
<td>Medicines Procurement</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>3.01.06.05</td>
<td>Medicines Distribution</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>3.01.06.06</td>
<td>Medicines Regulation</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>3.01.06.07</td>
<td>Pharmacovigilance</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>3.01.06.08</td>
<td>Rational Use of Medicines</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>3.01.06.09</td>
<td>Human Resource Development</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>3.01.06.10</td>
<td>Research</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>3.01.06.11</td>
<td>Monitoring and Evaluation</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>3.01.06.12</td>
<td>Traditional Medicine</td>
<td>Yes</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Yes</th>
<th>No</th>
<th>Year</th>
<th>WHO level</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.01.07</td>
<td>National medicines policy implementation plan exists. If yes, please write year of the most recent document.</td>
<td>Yes</td>
<td>No</td>
<td>2006</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.01.08</td>
<td>Policy or group of policies on clinical laboratories exist. If yes, please write year of the most recent document in the &quot;year&quot; field</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>3.01.09</td>
<td>National clinical laboratory policy implementation plan exists. If yes, please write year of the most recent document in the &quot;year&quot; field</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>3.01.10</td>
<td>Access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution or</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
| 3.01.11 | There are official written guidelines on medicines donations. | Yes | No | 2007 | WHO level 1 |
| 3.01.12 | Is pharmaceutical policy implementation being regularly monitored/assessed? | Yes | No | Ghana National Drugs Programme (GNDP) |
| 3.01.12.01 | Who is responsible for pharmaceutical policy monitoring? | GNDP Manager |
| 3.01.13 | Is there a national goodgovernance 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 conflictofinterest issues in pharmaceutical affairs. | Yes | No |
| 3.01.15 | There is a formal code of conduct for public officials. | Yes | No |
| 3.01.16 | Is there a whistle-blowing mechanism allowing individuals to raise a concern about wrongdoing occurring in the pharmaceutical sector of your country (ombudsperson)? | Yes | No |
| 3.01.16.01 | Please describe: |
| 3.01.17 | Comments and References | Ghana National Drug Policy, available at: http://apps.who.int/medicinedocs/documents/s16185e/s16185e.pdf |

Pharmaceutical Sector Country Profile Questionnaire.
# Section 4 Medicines Trade and Production

## 4.00 Respondent Information Section 4

<table>
<thead>
<tr>
<th>4.00.01</th>
<th>Name of person responsible for filling out this section of the instrument</th>
<th>Martha Gyansa-Lutterodt</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.00.02</td>
<td>Phone number</td>
<td>233244328787</td>
</tr>
<tr>
<td>4.00.03</td>
<td>Email address</td>
<td><a href="mailto:mlutterdt3@yahoo.com">mlutterdt3@yahoo.com</a></td>
</tr>
<tr>
<td>4.00.04</td>
<td>Other respondents for filling out this section</td>
<td></td>
</tr>
</tbody>
</table>

## 4.01 Intellectual Property Laws and Medicines

### Core questions [*click here for help*]

<p>| 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 1 |
| 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 | Patent office Registrar General, Attorney General, Ministries |
| 4.01.03.02 | Please provide URL | | |
| 4.01.04 | National Legislation has been modified to implement the TRIPS Agreement | Yes | No | 2010 | Ministry of Trade &amp; Industry |
| 4.01.05 | Current laws contain (TRIPS) flexibilities and safeguards | Yes | No | | awaiting parliamenta |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>4.01.06</td>
<td>Country is eligible for the transitional period to 2016</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>4.01.07</td>
<td>Which of the following (TRIPS) flexibilities and safeguards are present in the national law?</td>
<td>2007</td>
<td>WHO level 1</td>
</tr>
<tr>
<td>4.01.07.01</td>
<td><strong>Compulsory licensing</strong> provisions that can be applied for reasons of public health</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>4.01.07.02</td>
<td><strong>Bolar exception</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.01.08</td>
<td>Are <strong>parallelimporting</strong> provisions present in the national law?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>4.01.09</td>
<td>The country is engaged in initiatives to strengthen capacity to manage and apply intellectual property rights to contribute to innovation and promote public health</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>4.01.10</td>
<td>Are there legal provisions for <strong>data exclusivity</strong> for pharmaceuticals</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>4.01.11</td>
<td>Legal provisions exist for <strong>patent</strong> extension</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>4.01.12</td>
<td>Legal provisions exist for linkage between patent status and <strong>Marketing Authorization</strong></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>4.01.13</td>
<td>Comments and References</td>
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### 4.02 Manufacturing

**Core questions** ([click here for help](#))

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<tr>
<th></th>
<th></th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.02.01</td>
<td>Number of licensed pharmaceutical manufacturers in the country</td>
<td>34</td>
<td>2005 MoH Ghana (2005) Improving Access to</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
| 4.02.02 | Country has manufacturing capacity | Yes | No | Unknown | 2007 | WHO level I |
| 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 |
| 4.02.04 | Comments and References | Refer to UNIDO paper GTZ report | | | | |

Pharmaceutical Sector Country Profile Questionnaire.
<table>
<thead>
<tr>
<th>Questions</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>manufacturers (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.02.06S Number of multinational pharmaceutical companies manufacturing</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>medicines locally</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.02.07S Number of manufacturers that are GoodManufacturingPractice</td>
<td>34</td>
<td></td>
</tr>
<tr>
<td>(GMP) certified</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.02.08S Comments and References</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 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 | Mrs Amartey, Deputy CEO Drugs, FDB Ghana |
| 5.00.02 | Phone number |
| 5.00.03 | Email address |
| 5.00.04 | Other respondents for filling out this section | Mr Seneke, Registration department - 233244571563 |

#### 5.01 Regulatory Framework

**Core questions** ([Click here for help])

<table>
<thead>
<tr>
<th>Question</th>
<th>Year</th>
<th>Source</th>
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</thead>
<tbody>
<tr>
<td>5.01.01</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>5.01.02</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>5.01.03</td>
<td>Food and Drugs Board (FDB), Ghana, P O Box CT 2783, Accra. <a href="http://www.fdbghana.gov.gh">www.fdbghana.gov.gh</a></td>
<td>If yes, please provide name and address of the Medicines regulatory authority</td>
</tr>
<tr>
<td>5.01.04</td>
<td>The Medicines Regulatory Authority:</td>
<td></td>
</tr>
<tr>
<td>5.01.04.01</td>
<td>Part of MoH</td>
<td>Yes</td>
</tr>
<tr>
<td>5.01.04.02</td>
<td>Semi autonomous agency</td>
<td>Yes</td>
</tr>
<tr>
<td>5.01.04.03</td>
<td>Other (please specify)</td>
<td>not semi autonomous</td>
</tr>
<tr>
<td>5.01.05</td>
<td>What are the functions of the National Medicines Regulatory Authority?</td>
<td></td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.

30
| 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 | 316 | 2011 | Food and Drugs Board, Ghana |
| 5.01.06.01 | Date of response | 24.06.2011 | |
| 5.01.07 | The MRA has its own website | Yes | No | 2009 | WHO |
| 5.01.07.01 | - If yes, please provide MRA website address (URL) | http://www.fdbghana.gov.gh/ | | |
| 5.01.08 | The MRA receives external technical assistance | Yes | No | |
| 5.01.08.01 | If yes, please describe: | Proficiency testing with USP Training, participation in WHO prequalification, dossier evaluation and inspections | | |
| 5.01.09 | The MRA is involved in harmonization/collaboration initiatives | Yes | No | 2007 | WHO level 1 |
| 5.01.09.01 | - If yes, please specify | WAHO Harmonisation of registration and inspection requierments | | |
| 5.01.10 | An assessment of the medicines regulatory system has been made | Yes | No | |

Pharmaceutical Sector Country Profile Questionnaire.
Conducted in the last five years.

| 5.01.11 | Medicines Regulatory Authority gets funds from regular budget of the government. | Yes | No | 2007 | WHO level 1 |
| 5.01.12 | Medicines Regulatory Authority is funded from fees for services provided. | Yes | No | 2007 | WHO level 1 |
| 5.01.13 | Medicines Regulatory Authority receives funds/support from other sources | Yes | No | 2007 | WHO level 1 |
| 5.01.13.01 | - If yes, please specify | USP helping to control quality of antimalarials, Global Fund to control quality and safety |
| 5.01.14 | Revenues derived from regulatory activities are kept with the Regulatory Authority | Yes | No |  |  |
| 5.01.15 | The Regulatory Authority is using a computerized information management system to store and retrieve information on registration, inspections, etc. | Yes | No |  | Food and Drugs Board |
| 5.01.16 | Comments and References | Revenue derived goes to the consolidated funds of government. Information was derived from key informants |

### 5.02 Marketing Authorization (Registration)

**Core questions** *(click here for help)*

| 5.02.01 | Legal provisions require a Marketing Authorization (registration) for all pharmaceutical products on the market | Yes | No | 2007 | WHO level 1 |
| 5.02.02 | Are there any mechanism for exception/waiver of registration? | Yes | No |  | Food and Drugs Board |

Pharmaceutical Sector Country Profile Questionnaire.
| 5.02.03 | Are there mechanisms for recognition of registration done by other countries | Yes | No | Food and Drugs Board |
| 5.02.03.01 | If yes, please explain: | | | |
| 5.02.04 | Explicit and publicly available criteria exist for assessing applications for Marketing Authorization of pharmaceutical products | Yes | No | 2009 | Food and Drugs Board |
| 5.02.05 | Information from the prequalification programme managed by WHO is used for product registration | Yes | No | | Food and Drugs Board |
| 5.02.06 | Number of pharmaceutical products registered in your country | 2488 | | 2011 | Available at www.fdbghana.gov.gh/images/pdf/DrugReg_March21.pdf |
| 5.02.07 | Legal provisions require the MRA to make the list of registered pharmaceuticals with defined periodicity publicly available | Yes | No | 2009 | MeTA Pharmaceutical Sector Scanl |
| 5.02.07.01 | If yes, how frequently updated | | | updated every two months |
| 5.02.07.02 | If yes, please provide updated list or URL * | | | | www.fdbghana.gov.gh/images/pdf/DrugReg_March21.pdf |
| 5.02.08 | Medicines registration always includes the INN(InternationalNon-proprietary Names) | Yes | No | 2007 | WHO level 1 |
| 5.02.09 | Legal provisions require the payment of a fee for Medicines Marketing Authorization (registration) applications | Yes | No | 2009 | Food and Drugs Board |
| 5.02.10 | Comments and References | | | | Part of the MRAs regulations |

Pharmaceutical Sector Country Profile Questionnaire.
### Supplementary questions (*click here for help*)

| 5.02.11S | Legal provisions require Marketing Authorization holders to provide information about variations to the existing Marketing Authorization | Yes ☒ No ☐ | Food and Drugs Board |
| 5.02.12S | Legal provisions require publication of a Summary of Product Characteristics (SPCs) of the medicines registered | Yes ☒ No ☐ | Food and Drugs Board |
| 5.02.13S | Legal provisions require the establishment of an expert committee involved in the marketing authorization process | Yes ☒ No ☐ | 2007 WHO level 1 |
| 5.02.14S | Certificate of Pharmaceutical Products in accordance with the WHO Certification scheme is required as part of the Marketing Authorization application | Yes ☒ No ☐ | 2007 WHO level 1 |
| 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 ☐ | 2009 Food and Drugs Board |
| 5.02.16S | Legal provisions allow applicants to appeal against MRAs decisions | Yes ☒ No ☐ | 2009 Food and Drugs Board |
| 5.02.17S | Registration fee - the amount per application for a pharmaceutical product containing New Chemical Entity (NCE) (US$) | 4500 | 2009 Food and Drugs Board |
| 5.02.18S | Registration fee - the amount per application for a generic pharmaceutical product (US$) | 3000 | 2009 Food and Drugs Board |
| 5.02.19S | Time limit for the assessment of a Marketing Authorization application | 4.5 | 2009 Food and Drugs Board |

Pharmaceutical Sector Country Profile Questionnaire.
Table 5.02.20S: Comments & References
Average length of time for assessment is 180 days for patented products and 90 days for generics.

### 5.03 Regulatory Inspection

#### Core Questions

<table>
<thead>
<tr>
<th>Core Question</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.03.01 Legal provisions exist allowing for appointment of government pharmaceutical inspectors</td>
<td>Yes</td>
<td>1994</td>
</tr>
<tr>
<td>5.03.02 Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed</td>
<td>Yes</td>
<td>2007</td>
</tr>
<tr>
<td>5.03.02.01 If yes, legal provisions exist requiring inspections to be performed</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>5.03.03 Inspection is a pre-requisite for licensing of:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.03.03.01 Public facilities</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>5.03.03.02 Private facilities</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>5.03.04 Inspection requirements are the same for public and private facilities</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>5.03.05.01 Local manufactures are inspected for GMP compliance</td>
<td>Yes</td>
<td>2007</td>
</tr>
<tr>
<td>5.03.05.02 Private wholesalers are inspected</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>5.03.05.03 Retail distributors are inspected</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>5.03.05.04 Public pharmacies and stores are inspected</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>5.03.05.05 Pharmacies and dispensing points of health facilities are inspected</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
### 5.03.05.06
Please provide details on frequency of inspections for the different categories of facilities

**at least once a year**

### 5.03.06
Comments and References

Pharmacy council is mandated legally to inspect pharmacies, chemical sellers shops and facilities where drugs are dispensed, it does not licence nor inspect public and private pharmacies. Public pharmacies are sometimes inspected by the Director of Pharmacy's outfit as part of monitoring and supervision functions. FDB mostly inspects factories, warehouses and does post market surveillance.

### 5.04 Import Control

**Core Questions (click here for help)**

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.04.01</td>
<td>Legal provisions exist requiring authorization to import medicines</td>
</tr>
<tr>
<td>5.04.02</td>
<td>Legal provisions exist allowing the sampling of imported products for testing</td>
</tr>
<tr>
<td>5.04.03</td>
<td>Legal provisions exist requiring importation of medicines through authorized ports of entry</td>
</tr>
<tr>
<td>5.04.04</td>
<td>Legal provisions exist allowing inspection of imported pharmaceutical products at the authorized ports of entry</td>
</tr>
<tr>
<td>5.04.05</td>
<td>Comments and References</td>
</tr>
</tbody>
</table>

### 5.05 Licensing

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.05.01</td>
<td>Legal provisions exist requiring manufacturers to be licensed</td>
</tr>
<tr>
<td>5.05.02</td>
<td>Legal provisions exist requiring both domestic and international manufacturers to comply with Good</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
<th>Yes</th>
<th>No</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.05.02.01</td>
<td>If no, please explain</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.05.03</td>
<td>GMP requirements are published by the government.</td>
<td>Yes</td>
<td>No</td>
<td>2009</td>
<td>MeTA Pharmaceutical Scan</td>
</tr>
<tr>
<td>5.05.04</td>
<td>Legal provisions exist requiring importers to be licensed</td>
<td>Yes</td>
<td>No</td>
<td>2007</td>
<td>WHO level 1</td>
</tr>
<tr>
<td>5.05.05</td>
<td>Legal provisions exist requiring wholesalers and distributors to be licensed</td>
<td>Yes</td>
<td>No</td>
<td>2007</td>
<td>WHO level 1</td>
</tr>
<tr>
<td>5.05.06</td>
<td>Legal provisions exist requiring wholesalers and distributors to comply with <a href="#">GoodDistributing Practices</a> When filling in this part, please also fill in the relevant questions in the procurement and distribution section (Section 7)</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td>Food and Drugs Board</td>
</tr>
<tr>
<td>5.05.07</td>
<td>National Good Distribution Practice requirements are published by the government</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td>*Pharmacy Council</td>
</tr>
<tr>
<td>5.05.08</td>
<td>Legal provisions exist requiring pharmacists to be registered</td>
<td>Yes</td>
<td>No</td>
<td>1994</td>
<td>Pharmacy Act 489</td>
</tr>
<tr>
<td>5.05.09</td>
<td>Legal provisions exist requiring private pharmacies to be licensed</td>
<td>Yes</td>
<td>No</td>
<td>1994</td>
<td>Pharmacy Act 489</td>
</tr>
<tr>
<td>5.05.10</td>
<td>Legal provision exist requiring public pharmacies to be licensed</td>
<td>Yes</td>
<td>No</td>
<td>1994</td>
<td>Pharmacy Act 489</td>
</tr>
<tr>
<td>5.05.11</td>
<td>National Good Pharmacy Practice Guidelines are published by the government</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td>OCP</td>
</tr>
<tr>
<td>5.05.12</td>
<td>Legal provisions require the publication of a list of all licensed pharmaceutical facilities</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td>Pharmacy Council</td>
</tr>
<tr>
<td>5.05.13</td>
<td>Comments and References</td>
<td>OCP=Office of the Chief Pharmacist and Director of</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
Pharmaceutical Services has publish Standards for pharmaceutical care for public pharmacist.

The pharmacy act requires the licensing of premises for pharmacy practices, but the Council does not apply this rule to public facilities

All pharmaceutical facilities are required to be gazzetted

Pharmacy Council = personal communication from Mr Amaning Danquah of Pharmacy Council

### 5.06 Market Control and Quality Control

#### Core Questions ([click here for help](#))

<table>
<thead>
<tr>
<th>Question</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal Provisions for regulating the pharmaceutical market exist</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Does a laboratory exist in the country for Quality Control testing?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>If yes, is the laboratory part of the MRA?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Does the regulatory authority contract services elsewhere?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>If yes, please describe</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there any national laboratory accepted for collaboration with WHO prequalification Programme? Please describe.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicines are tested:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>For quality monitoring in the public sector (routine sampling in pharmacy stores and health facilities)</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>For quality monitoring in private sector (routine sampling in retail)</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>
### 5.06.03 When there are complaints or problem reports
| Yes | No |

### 5.06.04 For product registration
| Yes | No |

### 5.06.05 For public procurement prequalification
| Yes | No |

### 5.06.06 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 |

#### Related Question
How many Quality Control samples were taken for testing in the last two years?

### 5.06.06 How many Quality Control samples were taken for testing in the last two years?
| 2525 |

#### Related Question
Total number of samples tested in the last two years that failed to meet quality standards

### 5.06.07 Total number of samples tested in the last two years that failed to meet quality standards
| 142 |

#### Related Question
Results of quality testing in past two years are publicly available

### 5.06.08 Results of quality testing in past two years are publicly available
| Yes | No |

#### Related Question
Comments and References

### 5.06.09 Comments and References
Food and Drugs Board, Information obtained from key informants

---

### 5.07 Medicines Advertising and Promotion

#### Core Questions

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>WHO level 1</td>
</tr>
</tbody>
</table>

### 5.07.01 Legal provisions exist to control the promotion and/or advertising of prescription medicines
| Yes | No |

### 5.07.02 Who is responsible for regulating, promotion and/or advertising of medicines? Please describe:
Food and Drugs Board

---

Pharmaceutical Sector Country Profile Questionnaire.
| 5.07.03 | Legal provisions prohibit direct advertising of prescription medicines to the public | Yes  No | 2007 | WHO level 1 |
| 5.07.04 | Legal provisions require a pre-approval for medicines advertisements and promotional materials | Yes  No | 2007 | WHO level 1 |
| 5.07.05 | Guidelines/Regulations exist for advertising and promotion of non-prescription medicines | Yes  No | 2007 | WHO level 1 |
| 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 | 2009 | [http://www.dbghana.gov.gh/pdf/drugs/ADVE RTISEMEN T%20OF% 20DRUGS, %20COSM ETICS,%20 HOUSEHO LD% 20CHEMIC ALS%20& %20MEDIC AL%20DE VICES.pdf](http://www.dbghana.gov.gh/pdf/drugs/ADVE RTISEMEN T%20OF% 20DRUGS, %20COSM ETICS,%20 HOUSEHO LD% 20CHEMIC ALS%20& %20MEDIC AL%20DE VICES.pdf) |
| 5.07.06.01 | If yes, the [codeofconduct](http://www.dbghana.gov.gh/pdf/drugs/ADVE RTISEMEN T%20OF% 20DRUGS, %20COSM ETICS,%20 HOUSEHO LD% 20CHEMIC ALS%20& %20MEDIC AL%20DE VICES.pdf) 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 |т

Pharmaceutical Sector Country Profile Questionnaire.
### 5.08 Clinical trials

#### Core Questions ([click here for help](#))

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
<th>Question</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.08.01</td>
<td>Food and Drugs Board</td>
<td>Legal provisions exist requiring authorization for conducting <a href="#">Clinical Trials</a> by the MRA</td>
<td>Yes/No</td>
</tr>
<tr>
<td>5.08.02</td>
<td>Food and Drugs Board</td>
<td>Legal provisions exist requiring the agreement by an <a href="#">ethicscommittee/institutional review board</a> of the Clinical Trials to be performed</td>
<td>Yes/No</td>
</tr>
<tr>
<td>5.08.03</td>
<td>Food and Drugs Board</td>
<td>Legal provisions exist requiring registration of the clinical trials into international/national/regional registry</td>
<td>Yes/No</td>
</tr>
</tbody>
</table>

#### Supplementary questions ([click here for help](#))

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
<th>Question</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.08.05S</td>
<td>Food and Drugs Board</td>
<td>Legal provisions exist for GMP compliance of investigational products</td>
<td>Yes ✗ No ☐</td>
</tr>
<tr>
<td>5.08.06S</td>
<td>Food and Drugs Board</td>
<td>Legal provisions require sponsor, investigator to comply with <a href="#">Good Clinical Practices</a> (GCP)</td>
<td>Yes ☐ No ✗</td>
</tr>
<tr>
<td>5.08.07S</td>
<td>Food and Drugs Board</td>
<td>National GCP regulations are published by the Government.</td>
<td>Yes ☐ No ☐</td>
</tr>
</tbody>
</table>

---

Pharmaceutical Sector Country Profile Questionnaire.

41
### 5.09 Controlled Medicines

#### Core Questions ([click here for help](#))

<table>
<thead>
<tr>
<th>Code</th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Date</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.09.01</td>
<td>The country has adopted the following conventions:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.09.01.01</td>
<td>Single Convention on Narcotic Drugs, 1961</td>
<td>Yes</td>
<td>No</td>
<td>1964</td>
<td>Internation al Narccotics Control Board</td>
</tr>
<tr>
<td>5.09.01.02</td>
<td>The 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961</td>
<td>Yes</td>
<td>No</td>
<td>1990</td>
<td>Internation al Narccotics Control Board</td>
</tr>
<tr>
<td>5.09.01.03</td>
<td>Convention on Psychotropic Substances 1971</td>
<td>Yes</td>
<td>No</td>
<td>1990</td>
<td>Internation al Narccotics Control Board</td>
</tr>
<tr>
<td>5.09.01.04</td>
<td>United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988</td>
<td>Yes</td>
<td>No</td>
<td>1990</td>
<td>Internation al Narccotics Control Board</td>
</tr>
<tr>
<td>5.09.02</td>
<td>Laws for the control of narcotic and psychotropic substances, and precursors exist</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.09.03</td>
<td>Annual consumption of Morphine (mg/capita)</td>
<td>0.071</td>
<td></td>
<td>2010</td>
<td>Food and Drugs Board</td>
</tr>
<tr>
<td>5.09.04</td>
<td>Comments and References</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
## Supplementary questions (click here for help)

<table>
<thead>
<tr>
<th>5.09.05S</th>
<th>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</th>
<th>Yes ☐ No ☐ Unknown ☑</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.09.05.01S</td>
<td>If yes, year of review</td>
<td></td>
</tr>
<tr>
<td>5.09.06S</td>
<td>Annual consumption of Fentanyl (mg/capita)</td>
<td>0.000011</td>
</tr>
<tr>
<td>5.09.07S</td>
<td>Annual consumption of Pethidine (mg/capita)</td>
<td>0.036</td>
</tr>
<tr>
<td>5.09.08S</td>
<td>Annual consumption of Oxycodone (mg/capita)</td>
<td></td>
</tr>
<tr>
<td>5.09.09S</td>
<td>Annual consumption of Hydrocodone (mg/capita)</td>
<td></td>
</tr>
<tr>
<td>5.09.10S</td>
<td>Annual consumption of Phenobarbital (mg/capita)</td>
<td>82.1</td>
</tr>
<tr>
<td>5.09.11S</td>
<td>Annual consumption of Methadone (mg/capita)</td>
<td></td>
</tr>
<tr>
<td>5.09.12S</td>
<td>Comments and References</td>
<td></td>
</tr>
</tbody>
</table>

## 5.10 Pharmacovigilance

### Core Questions (click here for help)

| 5.10.01 | There are legal provision in the Medicines Act that provides for pharmacovigilance activities as part | Yes ☐ No ☑ |

Pharmaceutical Sector Country Profile Questionnaire.
| 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 |
| 5.10.03 | Legal provisions about monitoring Adverse Drug Reactions (ADR) exist in your country | Yes | No |
| 5.10.04 | A national pharmacovigilance centre linked to the MRA exists in your country | Yes | No |
| 5.10.04.01 | If a national pharmacovigilance centre exists in your country, how many staff does it employ full-time | 10 |
| 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 |
| 5.10.06 | A national Adverse Drug Reactions database exists in your country | Yes | No |
| 5.10.07 | How many ADR reports are in the database? | 2079 | 2010 |
| 5.10.08 | How many reports have been submitted in the last two years? | 1721 | 2010 |
| 5.10.09 | Are ADR reports set to the WHO | Yes | No |

Pharmaceutical Sector Country Profile Questionnaire.
A database in Uppsala?

<table>
<thead>
<tr>
<th>Date</th>
<th>Question</th>
<th>Reports</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.10.09.01</td>
<td>If yes, number of reports sent in the last two years</td>
<td>897</td>
<td>2010</td>
<td>Food and Drugs Board</td>
</tr>
<tr>
<td>5.10.10</td>
<td>Is there a national ADR or pharmacovigilance advisory committee able to provide technical assistance on causality assessment, risk assessment, risk management, case investigation and, where necessary, crisis management including crisis communication?</td>
<td>Yes No</td>
<td></td>
<td>Food and Drugs Board</td>
</tr>
<tr>
<td>5.10.11</td>
<td>Is there a clear communication strategy for routine communication and crises communication?</td>
<td>Yes No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.10.12</td>
<td>In the absence of a national pharmacovigilance system, ADRs are monitored in at least one public health program (for example TB, HIV, AIDS)?</td>
<td>Yes No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.10.13</td>
<td>Please describe how you intend to enhance the Pharmacovigilance system</td>
<td>Initiate consumer education and reporting, make safety reporting by industry a legal requirement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.10.14</td>
<td>Comments and References</td>
<td>Food and Drugs Board also serves as the national pharmacovigilance centre. Head office has 5 staff and the zonal centres have 5 staff</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Supplementary questions (click here for help)**

<table>
<thead>
<tr>
<th>Date</th>
<th>Question</th>
<th>Reports</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.10.15S</td>
<td>Feedback is provided to reporters</td>
<td>Yes No</td>
<td></td>
<td>Food and Drugs Board</td>
</tr>
<tr>
<td>5.10.16S</td>
<td>The ADR database is computerized</td>
<td>Yes No</td>
<td></td>
<td>Food and Drugs Board</td>
</tr>
<tr>
<td>5.10.17S</td>
<td>Medicationerrors(MEs) are reported</td>
<td>Yes No</td>
<td></td>
<td>Food and Drugs Board</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
| 5.10.18S | How many MEs are there in the ADRs database? |  |  
| 5.10.19S | There is a [riskmanagementplan](#) presented as part of product dossier submitted for Marketing Authorization? | Yes ☒ No ☐ | Food and Drugs Board  
| 5.10.20S | In the past two years, who has reported ADRs? |  |  
| 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 ☐ | Food and Drugs Board  
| 5.10.22S | Are there training courses in pharmacovigilance? | Yes ☒ No ☐ | Food and Drugs Board  
| 5.10.22.01S | If yes, how many people have been trained in the last two years? |  |  
| 5.10.23S | Comments and References |  |  

Pharmaceutical Sector Country Profile Questionnaire.
### Section 6 Medicines Financing

#### 6.00 Respondent Information Section 5

<table>
<thead>
<tr>
<th>6.00.01</th>
<th>Name of person responsible for filling out this section of the instrument</th>
<th>George K. Hedidor</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.00.02</td>
<td>Phone number</td>
<td>233244832111</td>
</tr>
<tr>
<td>6.00.03</td>
<td>Email address</td>
<td><a href="mailto:khedidor@yahoo.com">khedidor@yahoo.com</a></td>
</tr>
<tr>
<td>6.00.04</td>
<td>Other respondents for this sections</td>
<td></td>
</tr>
</tbody>
</table>

#### 6.01 Medicines Coverage and Exemptions

**Core Questions** ([Click here for help](#))

<table>
<thead>
<tr>
<th>6.01.01</th>
<th>Do the followings receive medicines free of charge:</th>
<th>2007</th>
<th>WHO level 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.01.01.01</td>
<td>Patients who cannot afford them</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>6.01.01.02</td>
<td>Children under 5</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>6.01.01.03</td>
<td>Pregnant women</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>6.01.01.04</td>
<td>Elderly persons</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>6.01.01.05</td>
<td>Please describe/explain your yes answers for questions above</td>
<td>The NHIA LI 1809 provides for exemptions for these categories</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6.01.02</th>
<th>Is there a public health system or social health insurance scheme or public programme providing medicines free of charge for:</th>
<th>2009</th>
<th>National Health Insurance Act, 2003 (Act 650) National Health Insurance Regulation s, 2004 (LI 1809)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.01.02.01</td>
<td>All medicines included in the EML</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.01.02.02 Any non-communicable diseases</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>6.01.02.03 Malaria medicines</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>6.01.02.04 Tuberculosis medicines</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>6.01.02.05 Sexually transmitted diseases medicines</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>6.01.02.06 HIV/AIDS medicines</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>6.01.02.07 Expanded Program on Immunization (EPI) vaccines</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>6.01.02.08 If others, please specify</td>
<td>Yes</td>
<td>Over 95% of disease conditions common in Ghana are covered by the insurance scheme</td>
</tr>
<tr>
<td>6.01.02.09 Please describe/explain your yes answers for questions above</td>
<td>Yes</td>
<td>Conditions covered are listed under the benefits package of the NHIS available at: <a href="http://www.nhis.gov.gh/?CategoryID=158&amp;ArticleID=120">http://www.nhis.gov.gh/?CategoryID=158&amp;ArticleID=120</a></td>
</tr>
<tr>
<td>6.01.03 Does a national health insurance, social insurance or other sickness fund provide at least partial medicines coverage?</td>
<td>Yes</td>
<td>2003 National Health Insurance Act 2003 (Act 650)</td>
</tr>
<tr>
<td>6.01.03.01 Does it provide coverage for medicines that are on the EML for inpatients</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>6.01.03.02 Does it provide coverage for medicines that are on the EML for outpatients</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>6.01.03.03 Please describe the medicines benefit of public/socialinsuranceschemes</td>
<td>Yes</td>
<td>Medicines benefit package is available at the url below. this list is updated 6monthly by the NHIA who reimburses for these medicines on the list. <a href="http://www.nhis.gov.gh/_Uploaeds/dbsAttachedFiles/MedicinesFinal.pdf">http://www.nhis.gov.gh/_Uploaeds/dbsAttachedFiles/MedicinesFinal.pdf</a></td>
</tr>
<tr>
<td>6.01.04 Do private health insurance schemes provide any medicines coverage?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>6.01.04.01 If yes, is it required to provide coverage for medicines that are on</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
the EML?


Private health schemes are not obliged to cover medicines on the EML which is public but medicines on the NHIA list.

### 6.02 Patients Fees and Copayments

*Core Questions ([click here for help](#))*

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.02.01</td>
<td>In your health system, at the point of delivery, are there any co-payment/fee requirements for consultations</td>
<td>Yes No</td>
<td>2007</td>
</tr>
<tr>
<td>6.02.02</td>
<td>In your health system, at the point of delivery, are there any co-payment/fee requirements for medicines</td>
<td>Yes No</td>
<td>2007</td>
</tr>
<tr>
<td>6.02.03</td>
<td>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?</td>
<td>Yes No</td>
<td>2007</td>
</tr>
<tr>
<td>6.02.03.01</td>
<td>Please describe the patient fees and copayments system</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.02.04</td>
<td>Comments and References</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 6.03 Pricing Regulation for the Private Sector

*Core Questions ([click here for help](#))*

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.03.01</td>
<td>Are there legal or regulatory provisions affecting pricing of</td>
<td>Yes No</td>
<td>2007</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
**6.03.01** If yes, are the provisions aimed at Manufacturers

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>WHO level 1</td>
</tr>
</tbody>
</table>

**6.03.02** If yes, are the provisions aimed at Wholesalers

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>WHO level 1</td>
</tr>
</tbody>
</table>

**6.03.03** If yes, are the provisions aimed at Retailers

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>MeTA Pharmaceutical Scan</td>
</tr>
</tbody>
</table>

**6.03.04** Please explain the positive answers above: (explain scope of provisions i.e generics vs. originator or subsets of medicines, EML etc.)

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>MeTA Pharmaceutical Scan</td>
</tr>
</tbody>
</table>

**6.03.05** Comments and References

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>MeTA Pharmaceutical Scan</td>
</tr>
</tbody>
</table>

---

**6.04 Prices, Availability and Affordability**

**Core Questions** *(click here for help)*

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>WHO/HAI Surveys of medicine prices and availability</td>
</tr>
</tbody>
</table>

**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

---

Pharmaceutical Sector Country Profile Questionnaire.
comment box to write some of the results and attach the report to the questionnaire

<table>
<thead>
<tr>
<th>Basket Of key medicines</th>
<th>Public procurement</th>
<th>Public patient</th>
<th>Private patient</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Availability (one or both of)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mean (%)</strong></td>
<td>Orig</td>
<td>6.04.01.01</td>
<td>6.04.01.03</td>
</tr>
<tr>
<td>LPG</td>
<td></td>
<td>6.04.01.02</td>
<td>6.04.01.04</td>
</tr>
<tr>
<td><strong>Median (%)</strong></td>
<td>Orig</td>
<td>6.04.02.01</td>
<td>6.04.02.03</td>
</tr>
<tr>
<td>LPG</td>
<td></td>
<td>6.04.02.02</td>
<td>6.04.02.04</td>
</tr>
<tr>
<td><strong>Price</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Median Price Ratio</strong></td>
<td>Orig</td>
<td>6.04.03.01</td>
<td>6.04.03.03</td>
</tr>
<tr>
<td>LPG</td>
<td></td>
<td>6.04.03.02</td>
<td>6.04.03.04</td>
</tr>
<tr>
<td><strong>Affordability</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Number of days’ wages</strong></td>
<td>Orig</td>
<td>6.04.04.01</td>
<td>6.04.04.03</td>
</tr>
<tr>
<td>LPG</td>
<td></td>
<td>6.04.04.02</td>
<td>6.04.04.04</td>
</tr>
</tbody>
</table>

6.04.05 Comments and References

6.05 Price Components and Affordability

Core Questions (click here for help)

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.05.01</td>
<td>Please state if a survey of medicines price components has been conducted in the past 5 years in your</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.

51
<table>
<thead>
<tr>
<th>6.05.02</th>
<th>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)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.05.03</td>
<td>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)</td>
</tr>
<tr>
<td>6.05.04</td>
<td>Comment and References</td>
</tr>
</tbody>
</table>

**Supplementary questions** ([click here for help](#))

<table>
<thead>
<tr>
<th>6.05.05S</th>
<th>Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the public sector (Median % contribution)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.05.06S</td>
<td>Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the private sector (Median % contribution)</td>
</tr>
<tr>
<td>6.05.07S</td>
<td>Median manufacturer selling price (CIF) as percent of final medicine price for a basket of key medicines (%)</td>
</tr>
<tr>
<td>6.05.08S</td>
<td>Median wholesaler selling price as percent of final medicine price for a basket of key medicines (%)</td>
</tr>
<tr>
<td>6.05.09S</td>
<td>Median pharmacist mark-up or dispensingfee as percent of retail price for a basket of key medicines (%)</td>
</tr>
<tr>
<td>6.05.10S</td>
<td>Median percentage contribution of the wholesalemarch-up to final medicine price for a basket of key medicines (in</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.

52
| 6.05.11S | Median percentage contribution of the *retailmark-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](#))

| 6.06.01 | There are *duties* on imported *active pharmaceutical ingredients* (APIs) | Yes | No | 2009 | Food and Drugs Board; National Health Insurance Authority |
| 6.06.02 | There are duties on imported *finished products* | Yes | No | 2009 | Food and Drugs Board; National Health Insurance Authority |
| 6.06.03 | **VAT (value-added tax)** or any other tax is levied on finished pharmaceuticals products | Yes | No | 2009 | Food and Drugs Board; National Health Insurance Authority |
| 6.06.04 | There are provisions for tax exceptions or waivers for pharmaceuticals and health products | Yes | No |
| 6.06.05 | Please specify categories of pharmaceuticals on which the taxes are applied and describe the |

Pharmaceutical Sector Country Profile Questionnaire.
<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.06.06</td>
<td>Comments and References</td>
<td>Exemptions and waivers that exist</td>
</tr>
</tbody>
</table>

**Supplementary questions** ([click here for help](#))

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.06.07S</td>
<td></td>
<td>Duty on imported active pharmaceutical ingredients, APIs (%)</td>
</tr>
<tr>
<td>6.06.08S</td>
<td></td>
<td>Duty on imported finished products (%)</td>
</tr>
<tr>
<td>6.06.09S</td>
<td></td>
<td>VAT on pharmaceutical products (%)</td>
</tr>
<tr>
<td>6.06.10S</td>
<td></td>
<td>Comments and References</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
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 | Samuel Boateng |
| 7.00.02 | Phone number | 0244269336 |
| 7.00.03 | Email address | samuel.boateng@moh.gov.gh |
| 7.00.04 | Other respondents for filling out this section | George Hedidor |

7.01 Public Sector Procurement

Core Questions [click here for help]

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

Pharmaceutical Sector Country Profile Questionnaire
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes/No</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>A government procurement agency which procures all public goods</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public sector requests for tender documents are publicly available</td>
<td>Yes</td>
<td>2009</td>
<td>MeTA Pharmaceutical Scan</td>
</tr>
<tr>
<td>Public sector tender awards are publicly available</td>
<td>Yes</td>
<td>2009</td>
<td>MeTA Pharmaceutical Scan</td>
</tr>
<tr>
<td>Procurement is based on prequalification of suppliers</td>
<td>Yes</td>
<td></td>
<td>Dir P&amp;S</td>
</tr>
<tr>
<td>If yes, please describe how it works</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comments and References</td>
<td></td>
<td></td>
<td>Director, Procurement &amp; Supply (P&amp;S): Mr Samuel Boateng</td>
</tr>
</tbody>
</table>

**Supplementary questions (click here for help)**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes/No</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there a written public sector procurement policy? If yes, please write the year of approval in the &quot;year&quot; field</td>
<td>Yes</td>
<td>2003</td>
<td></td>
</tr>
<tr>
<td>Are there legal provisions giving priority in public procurement to goods produced by local manufacturers?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The key functions of the procurement unit and those of the tender committee are clearly separated</td>
<td>Yes</td>
<td>2009</td>
<td>MeTA Pharmaceutical Sector Scan</td>
</tr>
<tr>
<td>A process exists to ensure the quality of products procured</td>
<td>Yes</td>
<td>2003</td>
<td>Manuals - Public Procurement Act, 2003 (Act available at 663)</td>
</tr>
<tr>
<td>If yes, the quality assurance process includes pre-qualification</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 7.02 Public Sector Distribution

#### Core Questions ([click here for help](#))

<table>
<thead>
<tr>
<th>7.02.01</th>
<th>The government supply system department has a Central Medical Store at National Level</th>
<th>Yes</th>
<th>No</th>
<th>2009</th>
<th>MeTA Pharmaceutical Scan</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.02.02</td>
<td>Number of public warehouses in the secondary tier of public distribution (State/Regional/Provincial)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.02.03</td>
<td>There are national guidelines on Good Distribution Practices (GDP)</td>
<td>Yes</td>
<td>No</td>
<td>2009</td>
<td>SSDM Unit of Ministry</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
<table>
<thead>
<tr>
<th>Question</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is a licensing authority that issues GDP licenses</td>
<td>2009</td>
<td>SSDM Unit of Ministry of Health</td>
</tr>
<tr>
<td>If a licensing authority exists, does it accredit public distribution facilities?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>List of GDP certified warehouses in the public sector exists</td>
<td>2009</td>
<td>SSDM Unit of Ministry of Health</td>
</tr>
<tr>
<td>List of GDP certified distributors in the public sector exists</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comments and References</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Supplementary questions (click here for help)**

<table>
<thead>
<tr>
<th>Question</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Which of the following processes is in place at the Central Medical Store:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forecasting of order quantities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes ☑ No ✗</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Requisition/Stock orders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes ☑ No ✗</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preparation of picking/packing slips</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes ☑ No ✗</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reports of stock on hand</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes ☑ No ✗</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reports of outstanding order lines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes ☑ No ✗</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiry dates management</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes ☑ No ✗</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Batch tracking</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes ☑ No ✗</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reports of products out of stock</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes ☑ No ✗</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percentage % availability of key medicines at the Central Medical Store</td>
<td>53</td>
<td>Dir P&amp;S</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
<table>
<thead>
<tr>
<th>7.02.10S</th>
<th>Average stock-out duration for a basket of medicines at the Central Medical Store, in days</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.02.11S</td>
<td>Routine Procedure exists to track the expiry dates of medicines at the Central Medical Store</td>
</tr>
<tr>
<td>7.02.12S</td>
<td>The Public Central Medical Store is GDP certified by a licensing authority</td>
</tr>
<tr>
<td>7.02.13S</td>
<td>The Public Central Medical Store is ISO certified</td>
</tr>
<tr>
<td>7.02.14S</td>
<td>The second tier public warehouses are GDP certified by a licensing authority</td>
</tr>
<tr>
<td>7.02.15S</td>
<td>The second tier public warehouses are ISO certified</td>
</tr>
<tr>
<td>7.02.16S</td>
<td>Comments and References</td>
</tr>
</tbody>
</table>

### 7.03 Private Sector Distribution

#### Core Questions ([click here for help](#))

<table>
<thead>
<tr>
<th>7.03.01</th>
<th>Legal provisions exist for licensing wholesalers in the private sector</th>
<th>Yes ☒ No ☐</th>
<th>1994</th>
<th>Pharmacy Act 489</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.03.02</td>
<td>Legal provisions exist for licensing distributors in the private sector</td>
<td>Yes ☒ No ☐</td>
<td>1994</td>
<td>Pharmacy Act 489</td>
</tr>
<tr>
<td>7.03.03</td>
<td>List of <a href="#">GDP</a> certified wholesalers in the private sector exists</td>
<td>Yes ☒ No ☐</td>
<td>2009</td>
<td>SSDM Unit of Ministry of Health</td>
</tr>
<tr>
<td>7.03.04</td>
<td>List of GDP certified distributors in the private sector exists</td>
<td>Yes ☒ No ☐</td>
<td>2009</td>
<td>SSDM Unit of Ministry of Health</td>
</tr>
<tr>
<td>7.03.05</td>
<td>Comments and References</td>
<td></td>
<td></td>
<td>Pharmacy Act 489</td>
</tr>
</tbody>
</table>
### Section 8 Selection and rational use

#### 8.00 Respondent Information Section 7

<table>
<thead>
<tr>
<th>8.00.01</th>
<th>Name of person responsible for filling out this section of the instrument</th>
<th>Saviour Yevutsey</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.00.02</td>
<td>Phone number</td>
<td>233244570354</td>
</tr>
<tr>
<td>8.00.03</td>
<td>Email address</td>
<td><a href="mailto:syevutsey@yahoo.com">syevutsey@yahoo.com</a></td>
</tr>
<tr>
<td>8.00.04</td>
<td>Other respondents for filling out this section</td>
<td>George Hedidor</td>
</tr>
</tbody>
</table>

#### 8.01 National Structures

**Core Questions** ([click here for help](#))

<table>
<thead>
<tr>
<th>8.01.01</th>
<th>National <a href="#">essentialmedicineslist</a> (EML) exists. If yes, please write year of last update of EML in the &quot;year&quot; field</th>
<th>Yes</th>
<th>No</th>
<th>2010</th>
<th>Essential Medicines List 6th edition</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.01.01.01</td>
<td>If yes, number of medicines on the EML (no. of INN)</td>
<td>334</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.01.01.02</td>
<td>If yes, there is a written process for selecting medicines on the EML</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.01.01.03</td>
<td>If yes, the EML is publicly available</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.01.01.04</td>
<td>If yes, is there any mechanism in place to align the EML with the Standard Treatment Guidelines (STG)</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.01.02</td>
<td>National Standard Treatment Guidelines (STGs) for most common illnesses are produced/endorsed by the MoH. If yes, please insert year of last update of STGs in the &quot;year&quot; field</td>
<td>Yes</td>
<td>No</td>
<td>2010</td>
<td>GNPD Ghana STG 2010</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire
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 | 2004 | WHO level 1  
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 | 2004 | WHO level 1  
8.01.05 | STGs specific to Paediatric conditions exist. Please use the "year" field to write the year of last update of paediatric condition STGs | Yes  No | 2007 | WHO level 1  
8.01.06 | % of public health facilities with copy of EML (mean)- Survey data | 75 | 2009 | Assessment of the Pharmaceutical Sector  
8.01.07 | % of public health facilities with copy of STGs (mean)- Survey data | 94.4 | 2009 | Assessment of the Pharmaceutical Sector  
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 1  
8.01.09 | Public education campaigns on rational medicine use topics have been conducted in the previous two years | Yes  No | | Ghana National Drugs Programme  
8.01.10 | A survey on rational medicine use has been conducted in the previous two years | Yes  No | 2009 | Assessment of the Pharmaceutical Sector  
8.01.11 | A national programme or committee (including government, civil society, and professional bodies) exists to monitor and | Yes  No | 2009 | Ghana National Drugs Programme  

Pharmaceutical Sector Country Profile Questionnaire.
promote rational use of medicines

| 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 1 |
| 8.01.13 | Comments and References | 334 INN drug ingredients and 725 different preparations of these ingredients. Source: EML 2010. There is only one STG used at all levels of care which also caters for all ages. Medicines in the EML 2010 are teased out of the STG 2010 |

**Supplementary questions** ([click here for help](#))

| 8.01.14S | The EssentialMedicinesList(EML) includes formulations specific for children | Yes ☒ No ☐ | 2010 | EML 2010 |
| 8.01.15S | There are explicitly documented criteria for the selection of medicines in the EML | Yes ☒ No ☐ | 2009 | Ghana National Drugs Programme |
| 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 1 |
| 8.01.16.01S | If yes, conflictofinterest declarations are required from members of national EML committee | Yes ☒ No ☐ |
| 8.01.17S | National medicines formulary exists | Yes ☒ No ☐ | 2007 | WHO level 1 |
| 8.01.18S | Is there a funded national inter-sectoral task force to coordinate the promotion of appropriate use of antimicrobials and prevention of spread of infection? | Yes ☐ No ☒ | 2007 | WHO level 1 |

Pharmaceutical Sector Country Profile Questionnaire.
8.02 Prescribing

Core Questions ([Click here for help])

<table>
<thead>
<tr>
<th>Question</th>
<th>Year</th>
<th>Source</th>
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</thead>
<tbody>
<tr>
<td>8.02.01 Legal provisions exist to govern the licensing and prescribing practices of prescriber</td>
<td></td>
<td>WHO level 1</td>
</tr>
<tr>
<td>8.02.02 Legal provisions exist to restrict dispensing by prescribers</td>
<td></td>
<td>National Drug Policy</td>
</tr>
<tr>
<td>8.02.03 Do prescribers in the private sector dispense medicines?</td>
<td></td>
<td>WHO level 1</td>
</tr>
<tr>
<td>8.02.04 Regulations require hospitals to organize/develop Drug and Therapeutics Committees (DTCs)</td>
<td></td>
<td>WHO level 1</td>
</tr>
<tr>
<td>8.02.05 Do more than half of referral hospitals have a DTC?</td>
<td></td>
<td>WHO level 1</td>
</tr>
<tr>
<td>8.02.06 Do more than half of general hospitals have a DTC?</td>
<td></td>
<td>WHO level 1</td>
</tr>
<tr>
<td>8.02.07 Do more than half of regions/provinces have a DTC?</td>
<td></td>
<td>WHO level 1</td>
</tr>
<tr>
<td>8.02.08 The core medical training curriculum includes components on:</td>
<td></td>
<td>WHO level 1</td>
</tr>
<tr>
<td>8.02.08.01 Concept of EML</td>
<td></td>
<td></td>
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<tr>
<td>8.02.08.02 Use of STGs</td>
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Pharmaceutical Sector Country Profile Questionnaire.
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Yes</th>
<th>No</th>
<th>Year</th>
<th>WHO level</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.02.08.03</td>
<td>Pharmacovigilance</td>
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<td></td>
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<td>8.02.08.04</td>
<td>Problem based pharmacotherapy</td>
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<td>8.02.09</td>
<td>Mandatory continuing education that includes pharmaceutical issues is required for doctors (see physician)</td>
<td>Yes</td>
<td>No</td>
<td>2007</td>
<td>WHO level 1</td>
</tr>
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<td>8.02.10</td>
<td>Mandatory continuing education that includes pharmaceutical issues is required for nurses</td>
<td>Yes</td>
<td>No</td>
<td></td>
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<td>8.02.11</td>
<td>Mandatory continuing education that includes pharmaceutical issues is required for paramedical staff</td>
<td>Yes</td>
<td>No</td>
<td>2007</td>
<td>WHO level 1</td>
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<td>8.02.12</td>
<td>Prescribing by INN name is obligatory in:</td>
<td></td>
<td></td>
<td>2007</td>
<td>WHO level 1</td>
</tr>
<tr>
<td>8.02.12.01</td>
<td>Public sector</td>
<td>Yes</td>
<td>No</td>
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<td>8.02.12.02</td>
<td>Private sector</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>8.02.13</td>
<td>Average number of medicines prescribed per patient contact in public health facilities (mean)</td>
<td></td>
<td></td>
<td>2009</td>
<td>Assessment Pharmaceutical Sector</td>
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<tr>
<td>8.02.14</td>
<td>% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)</td>
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<td></td>
<td>2009</td>
<td>Assessment Pharmaceutical Sector</td>
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<tr>
<td>8.02.15</td>
<td>% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)</td>
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<td></td>
<td>2009</td>
<td>Assessment Pharmaceutical Sector</td>
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<tr>
<td>8.02.16</td>
<td>% of patients in outpatient public health care facilities receiving antibiotics (mean)</td>
<td></td>
<td></td>
<td>2009</td>
<td>Assessment Pharmaceutical Sector</td>
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<tr>
<td>8.02.17</td>
<td>% of patients in outpatient public health care facilities receiving</td>
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<td></td>
<td>2009</td>
<td>Assessment Pharmaceutical Sector</td>
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Pharmaceutical Sector Country Profile Questionnaire.
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<th>Year</th>
<th>Source</th>
<th>Year</th>
<th>Source</th>
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<td>8.02.18</td>
<td>% of prescribed drugs dispensed to patients (mean)</td>
<td>2009</td>
<td>Assessment Pharmaceutical Sector</td>
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<td>8.02.19</td>
<td>% of medicines adequately labelled in public health facilities (mean)</td>
<td>7.2</td>
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<tr>
<td>8.02.20</td>
<td>Comments and References</td>
<td>WHO Pharmaceutical Situation Assessment – Level II Health Facilities Survey in Ghana. June 2009</td>
<td></td>
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**Supplementary questions** ([click here for help](#))

<table>
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<th>Year</th>
<th>Source</th>
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<tbody>
<tr>
<td>8.02.21S</td>
<td>A professional association code of conduct exists governing professional behaviour of doctors</td>
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<tr>
<td>8.02.22S</td>
<td>A professional association code of conduct exists governing professional behaviour of nurses</td>
</tr>
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<td>8.02.23S</td>
<td>Diarrhoea in children treated with Oral Rehydration Solution (ORS) (%)</td>
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<tr>
<td>8.02.24S</td>
<td>Comments and References</td>
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### 8.03 Dispensing

**Core Questions** ([click here for help](#))

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<tr>
<td>8.03.01</td>
<td>Legal provisions exist to govern dispensing practices of pharmaceutical personnel</td>
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<tr>
<td>8.03.02</td>
<td>The basic pharmacist training curriculum includes components on:</td>
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<tr>
<td>8.03.02.01</td>
<td>Concept of EML</td>
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</table>

Pharmaceutical Sector Country Profile Questionnaire.
<table>
<thead>
<tr>
<th></th>
<th>Use of STGs</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Drug Information</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Clinical pharmacology</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Medicines supply management</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>8.03.03</td>
<td>Mandatory continuing education that includes rational use of medicines is required for pharmacists</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>8.03.04</td>
<td><strong>Generic substitution</strong> at the point of dispensing in public sector facilities is allowed</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>8.03.05</td>
<td><strong>Generic substitution</strong> at the point of dispensing in private sector facilities is allowed</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>8.03.06</td>
<td>In practice, (even though this may be contrary to regulations) are antibiotics sometimes sold over-the-counter without any prescription?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>8.03.07</td>
<td>In practice, (even though this may be contrary to regulations) are injections sometimes sold over-the-counter without any prescription?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>8.03.08</td>
<td>Comments and References</td>
<td></td>
<td></td>
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</tbody>
</table>

**Supplementary questions (click here for help)**

<table>
<thead>
<tr>
<th></th>
<th>Year</th>
<th>Source</th>
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<tbody>
<tr>
<td>8.03.09S</td>
<td>2009</td>
<td>MeTA Pharmaceutical Scan</td>
</tr>
<tr>
<td></td>
<td>A professional association <strong>code of conduct</strong> exists governing professional behaviour of pharmacists</td>
<td>Yes</td>
</tr>
<tr>
<td>8.03.10S</td>
<td>2007</td>
<td>WHO level 1</td>
</tr>
<tr>
<td></td>
<td>In practice, (even though this may be contrary to regulations) do the following groups of staff sometimes prescribe <strong>prescription-only medicines</strong> at the primary care level</td>
<td></td>
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</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Answer</th>
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</thead>
<tbody>
<tr>
<td>8.03.10.01S</td>
<td>Nurses</td>
<td>Yes</td>
</tr>
<tr>
<td>8.03.10.02S</td>
<td>Pharmacists</td>
<td>Yes</td>
</tr>
<tr>
<td>8.03.10.03S</td>
<td>Paramedics</td>
<td>Yes</td>
</tr>
<tr>
<td>8.03.10.04S</td>
<td>Personnel with less than one month training</td>
<td>Yes</td>
</tr>
<tr>
<td>8.03.11S</td>
<td>Comments and References</td>
<td></td>
</tr>
</tbody>
</table>
### Section 9 Household data/access

#### 9.00 Respondent Information section 8

<table>
<thead>
<tr>
<th>9.00.01</th>
<th>Name of person responsible for filling out this section of the instrument</th>
<th>Saviour Yevutsey</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.00.02</td>
<td>Phone number</td>
<td>+233244570354</td>
</tr>
<tr>
<td>9.00.03</td>
<td>Email address</td>
<td><a href="mailto:syevutsey@yahoo.com">syevutsey@yahoo.com</a></td>
</tr>
<tr>
<td>9.00.04</td>
<td>Other respondents for filling out this section</td>
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</tr>
</tbody>
</table>

#### 9.01 Data from Household Surveys

**Core Questions** ([click here for help](#))

<table>
<thead>
<tr>
<th>9.01.01</th>
<th>What household surveys have been undertaken in the past 5 years to assess access to medicines?</th>
<th>WHO Level II House hold survey to measure access to and use of medicines in Ghana June 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.01.02</td>
<td>Adults with acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)</td>
<td>81</td>
</tr>
<tr>
<td>9.01.03</td>
<td>Adults with acute conditions not taking all medicines because they cannot afford them (%)</td>
<td>7</td>
</tr>
<tr>
<td>9.01.04</td>
<td>Adults (from poor households) with an acute health condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)</td>
<td>74</td>
</tr>
<tr>
<td>9.01.05</td>
<td>Adults (from poor households) with an acute condition in two-week recall period who did not take all medicines because they cannot</td>
<td>7</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Value</td>
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<td>--------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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<tr>
<td>9.01.06</td>
<td>Adults with chronic conditions taking all medicines prescribed by an authorized prescriber (%)</td>
<td>83</td>
</tr>
<tr>
<td>9.01.07</td>
<td>Adults (from poor households) with chronic conditions not taking all medicines because they cannot afford them (%)</td>
<td>1.2</td>
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<tr>
<td>9.01.08</td>
<td>Adults (from poor households) with chronic conditions who usually take all medicines prescribed by an authorized prescriber (%)</td>
<td>91.9</td>
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<tr>
<td>9.01.09</td>
<td>Children (from poor households) with an acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)</td>
<td>94.4</td>
</tr>
<tr>
<td>9.01.10</td>
<td>Percentage of people that obtained the medicines prescribed in the 15 days before the interview (%)</td>
<td></td>
</tr>
<tr>
<td>9.01.11</td>
<td>People that obtained prescribed medicines for free in the 15 days before the interview (%)</td>
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</tr>
<tr>
<td>9.01.12</td>
<td>Comments and References</td>
<td></td>
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</tbody>
</table>

**Supplementary questions (click here for help)**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Value</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.01.13S</td>
<td>Adults with acute conditions not taking all medicines because the medicines were not available (%)</td>
<td>84.0</td>
<td>2003</td>
<td>WHSurgery</td>
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<tr>
<td>9.01.14S</td>
<td>Adults with chronic conditions not taking all medicines because they</td>
<td>64.1</td>
<td>2003</td>
<td>WHSurgery</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
| 9.01.15S | Adults with chronic conditions not taking all medicines because the medicines were not available (%) | 35.9 | 2003 | WHSurvey |
| 9.01.16S | Children with acute conditions taking all medicines prescribed by an authorized prescriber (%) | 94.5 | 2003 | WHSurvey |
| 9.01.17S | Children with acute conditions not taking all medicines because they cannot afford them (%) | 41.1 | 2003 | WHSurvey |
| 9.01.18S | Children with acute conditions not taking all medicines because the medicines were not available (%) | 58.1 | 2003 | WHSurvey |
| 9.01.19S | Children (from poor households) with acute conditions not taking all medicines because they cannot afford them (%) | 35.2 | 2003 | WHSurvey |
| 9.01.20S | Comments and References |  |  |  |

Pharmaceutical Sector Country Profile Questionnaire.
## Key Documents to be attached

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