



## Pharmaceutical Sector Country Profile Questionnaire

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### The Pharmaceutical Sector Country Profile Survey

#### 1. Background and Rationale:

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

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

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

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

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

#### 2. What can Pharmaceutical Sector Country Profiles offer:

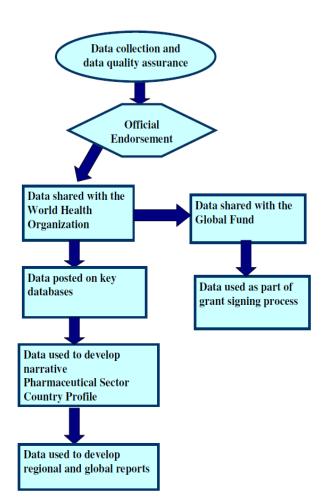
Completing this questionnaire will require the time of national experts and responsible officers but it is worthwhile as your country and your partners will benefit from it in a number of ways:

- I) The questionnaire offers a unique opportunity to consolidate, in one place, information that is available in different locations and institutions e.g. the National Medicines Regulatory Authority, Central Medical Stores, National Health Accounts, etc.
- II) The methodology proposed for filling in the questionnaire will ensure that good quality data are collected and that the source and date of information are known and reported.
- III) Data on structure, process and outcomes are collected, and the questionnaire has been pre-filled with data available in the public domain; indicators are divided into core and supplementary in order to make it easier to identify what is more important.
- IV) The data collected will highlight the strengths and weaknesses of the pharmaceutical sector and will be made available in a national database as official country information, for use by decision-makers, health and pharmaceutical experts, researchers and international partners and the public..
- V) The data collected could be transformed into a narrative report with robust data analysis and bibliographic references, that will summarize the medicines situation in the country.
- VI) Based on experiences from previous surveys, a detailed glossary of key definitions and a manual for use of the questionnaire have been developed and can be found at the end of the questionnaire.

#### 3. The process of data collection and analysis:

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

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



- **3.2 Official endorsement**. Once the questionnaire has been completed, the information contained in it should be officially endorsed and its disclosure authorized by a senior official in the Ministry of Health. This should be done by signing the formal endorsement form attached to the questionnaire. This will ensure that the quality of the information contained in the Pharmaceutical Sector Country Profile questionnaire is certified by the country.
- **3.3** Data shared with the Global Fund. Data collected from Global Fund priority countries will be shared with the Global Fund and it will be used as part of the Global Fund's own grant signing and implementation procedures.
- 3.4 Data posted on key databases. Data endorsed by the country will be posted on health databases (such as the WHO Global Health Observatory, <a href="http://www.who.int/gho/en/">http://www.who.int/gho/en/</a>), 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.

- <u>6. Comments:</u> comments fields allow the entry of free text to clarify or follow up on answers given. Please reference each comment by using the number of the question you are referring to (example: 2.01.02).
- 7. Year of data: year fields should be used to specify the year of the **data** used to answer the question. Only values between 1930 and 2011 will be accepted. Please use this column as follows:
  - When the source refers directly to a specific document (for example: 'Medicines Act' or 'EML'), please put in the publication year of the document (note: only the year and not a specific date can be entered).
  - When the source refers to a document that contains older data than the document itself, please put in the original year of the data. For example, when the total population for 2008 is extracted from the World Health Statistics 2010, please put 2008 in the 'year' column and 'World Health Statistics 2010' in the 'source' column.
  - When the source of the information is not a document, but the informant himself/herself, please put in the current year.

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

7.01.12S	Which of the following tender methods are used in public sector procurement		1998 Дон, 1998
7.01.12.01 S	National competitive tenders	Yes⊠ No 🗆	
7.01.12.02 S	International competitive tenders	Yes⊠ No 🗆	
7.01.12.03 S	Direct purchasing	Yes No 🗆	
7.01.138	Comments and References	National Drug Policy for South Africa , publis availabilt at: http://www.doh.gov.za/docs/pol	

- <u>9. Documents:</u> you will see in the questionnaire that we would like you to collect and share a number of key country documents that we believe would greatly enrich the country's profile content and these documents could be made available through countries and WHO web pages. Please attach the following documents, if available:
  - National Medicines Policy (NMP);
  - NMP implementation plan;
  - National Medicines Act;
  - National pharmaceutical Human Resources report or strategic plan;
  - Latest report on the national pharmaceutical market (any source);
  - Pharmacovigilance national centre report (including an Adverse Drug Reaction (ADR), analysis report produced in the last two years);
  - National pharmaceutical legislation or regulation;
  - Annual report of quality control laboratories;

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

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

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

These documents will be published on the WHO web site's medicines library (<a href="http://apps.who.int/medicinedocs/en/">http://apps.who.int/medicinedocs/en/</a>) 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.

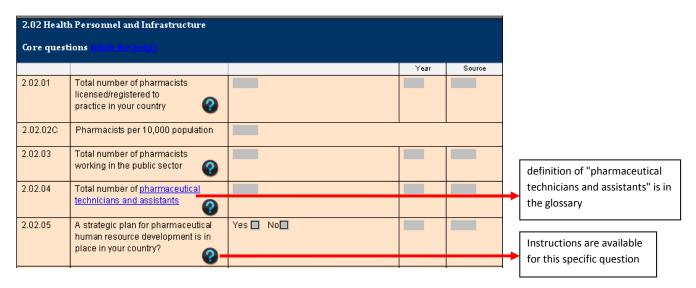
10. Attaching files to the questionnaire: please place all files to be attached in a single folder on your computer. Name the documents as follows: <short name of the document>.doc (example: EML.doc). Then compress (ZIP) the files and attach the compressed file with the completed instrument to the email. 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 <a href="http://hinfo.humaninfo.ro/medicinedocs/">http://hinfo.humaninfo.ro/medicinedocs/</a>, though the documents will only appear on the Medicines Documentation site at the beginning of the following month.

<u>11. Manual for use of the questionnaire:</u> 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. <u>Glossary</u>: 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 <a href="http://www.who.int/medicines/areas/coordination/coordination">http://www.who.int/medicines/areas/coordination/coordination</a> assessment/en/index1.html

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

#### 3.2 Intellectual Property Laws and Medicines

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

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

Compulsory licensing provisions that can be applied for reasons of public health



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	Section 0 General Info				
0.01 Con	0.01 Contact Info				
0.01.01	Country (precoded)	Sierra Leone			
0.01.02	Name coordinator	Ade T Renner			
0.01.03	Address (Street, City)	World Health Organization, 21a Riverside Drive, Brookfields. Freetown. Sierra Leone.			
0.01.04	Phone number	00232 76 611652			
0.01.05	Email address	rennera@sl.afro.who.int			
0.01.06	Web address	www.whosierraleone.org			
0.01.07	Institution	World Health Organization.			

#### Section 1 Health and Demographic data 1.00 Respondent Information Section 1 1.00.01 Name of person responsible for filling Dr Edward Magbity, Directorate of Planning and Information (DPI), out Survey section 1 MoH 1.00.02 Phone number 00 232 78 434 267 1.00.03 Email address magbity@gmail.com 1.00.04 Other respondents for filling out this section 1.01 Demographic and Socioeconomic Indicators Core questions (click here for help) Year Source 1.01.01 Population, total (,000) 2008 **WHS** 5,560 1.01.02 WHS Population growth rate (Annual %) 3.2 2008 1.01.03 Total Gross Domestic Product (GDP) 1,941.85 2008 World Bank (millions US\$) data 1.01.04 GDP growth (Annual %) World Bank 4.01 2008 data 1.01.05C GDP per capita (US\$ current IMF 781,594 2009 exchange rate) 1.01.06 Comments and References Supplementary questions (click here for help) Source Year 1.01.07S Population < 15 years (% of total 43 2008 WHS population) 1.01.08S Population > 60 years (% of total 4 2008 WHS population) 1.01.09S Urban population (% of total 2008 WHS 38

population)

1.01.10S	Fertility rate, total (Births per woman)	5.2	2008	WHS
1.01.11S	Population living with less than \$1.25/day (international PPP) (%)	53.37	2003	World Bank data
1.01.12S	Population living below nationally defined poverty line (%)	70.2	2004	World Bank data
1.01.13S	Income share held by lowest 20% of the population (% of national income)	6.09	2003	World Bank data
1.01.14S	Adult literacy rate, 15+ years (% of relevant population)	38	2008	WHS
1.01.15S	Comments and References	None		
1.02 Mor	stality and Causes of Death			
	rtality and Causes of Death stions (click here for help)			
			Year	Source
Core que		48	Year 2008	Source SLDHS
<b>Core que</b>	stions (click here for help)  Life expectancy at birth for men	48		
	Life expectancy at birth for men (Years)  Life expectancy at birth for women		2008	SLDHS

	(Years)		2000	020.10
1.02.02	Life expectancy at birth for women (Years)	50	2008	SLDHS
1.02.03	Infant mortality rate, between birth and age 1 (/1,000 live births)	89	2008	SLDHS
1.02.04	Under 5 mortality rate (/1,000 live births)	140	2008	SLDHS
1.02.05	Maternal mortality ratio (/100,000 live births)	857	2008	SLDHS
1.02.06	Please provide a list of top 10 diseases causing mortality			
1.02.06.01	Disease 1	n/a		
1.02.06.02	Disease 2	n/a		
1.02.06.03	Disease 3	n/a		

1.02.06.04	Disease 4	n/a		
1.02.06.05	Disease 5	n/a		
1.02.06.06	Disease 6	n/a		
1.02.06.07	Disease 7	n/a		
1.02.06.08	Disease 8	n/a		
1.02.06.09	Disease 9	n/a		
1.02.06.10	Disease 10	n/a		
1.02.07	Please provide a list of top 10 diseases causing morbidity			
1.02.07.01	Disease 1	Malaria		
1.02.07.02	Disease 2	Respiratory Infection	***************************************	
1.02.07.03	Disease 3	Anaemia		
1.02.07.04	Disease 4	Diarrhoea		
1.02.07.05	Disease 5	Clinical Malnutrition		
1.02.07.06	Disease 6	Worm Infectation		
1.02.07.07	Disease 7	Skin diseases		
1.02.07.08	Disease 8	Eye infection		
1.02.07.09	Disease 9	Wound		
1.02.07.10	Disease 10	Burns		
1.02.08	Comments and References	Official data not available on top 10 diseas	ses causing	mortality
Supplemen	ntary questions (click here for help	<u>)</u>		
			Year	Source
1.02.09S	Adult mortality rate for both sexes between 15 and 60 years (/1,000 population)	393	2008	WHS

1.02.10\$	Neonatal mortality rate (/1,000 live births)	45	2008	WHS
1.02.11S	Age-standardized mortality rate by non-communicable diseases (/100,000 population)	1033	2004	WHS
1.02.12\$	Age-standardized mortality rate by cardiovascular diseases (/100,000 population)	468	2009	WHS
1.02.13S	Age-standardized mortality rate by cancer (/100,000 population)	184	2009	WHS
1.02.14S	Mortality rate for HIV/AIDS (/100,000 population)	n/a		
1.02.15S	Mortality rate for tuberculosis (/100,000 population)	140	2008	WHS
1.02.16S	Mortality rate for Malaria (/100,000 population)	154	2006	WHS
1.02.17S	Comments and References	Mortality rate for HIV/AIDS per 100,000 is in progress to follow HIV patients.	not availab	le. Efforts are

#### **Section 2 Health Services** 2.00 Respondent Information Section 2 2.00.01 Dr Edward Magbity, Directorate of Planning and Information, MoH Name of person responsible for filling out this section of the instrument 2.00.02 Phone number 00 232 78 434 267 2.00.03 Email address magbity@gmail.com 2.00.04 Other respondents for filling out this Mr Wilshire Johnson, Registrar, Pharmacy Board of Sierra Leone, section Mr Mike Dauda, Ministry of Finance and Economic Development 2.01 Health Expenditures Core questions (click here for help) Year Source 2.01.01.01 NHA data Total annual expenditure on health 2008 242,936.56 (millions NCU) 2.01.01.02 81.48 NHA data Total annual expenditure on health 2008 (millions US\$ average exchange rate) 2.01.02C Total health expenditure as % of 4.17 **Gross Domestic Product** 2.01.03.01C Total annual expenditure on health 46,693.63 per capita (NCU) 2.01.03.02C Total annual expenditure on health 14.65 per capita (US\$ average exchange rate) 2.01.04.01 69,201.78 NHA data General government annual 2008 expenditure on health (millions NCU) 2.01.04.02 General government annual 23.21 NHA data 2008 expenditure on health (millions US\$ average exchange rate) 2.01.05 Government annual expenditure on 7.82 2008 NHA data health as percentage of total

government budget (% of total

government budget)

2.01.06C	Government annual expenditure on health as % of total expenditure on health (% of total expenditure on health)	28.49	2008	NHA data
2.01.07.01C	Annual per capita government expenditure on health (NCU)	12,446.36		
2.01.07.02C	Annual per capita government expenditure on health (US\$ average exchange rate)	4.17		
2.01.08C	Private health expenditure as % of total health expenditure (% of total expenditure on health)	71.51	2008	NHA data
2.01.09	Population covered by a public health service or public health insurance or social health insurance, or other sickness funds of total population)	Data not available		
2.01.10	Population covered by private health insurance (% of total population)	Data not available		
2.01.11.01	Total pharmaceutical expenditure (millions NCU)	0		
2.01.11.02	Total pharmaceutical expenditure (millions US\$ current exchange rate)	0		
2.01.12.01C	Total pharmaceutical expenditure per capita (NCU)	PREFILL CALC		
2.01.12.02C	Total pharmaceutical expenditure per capita (US\$ current exchange rate)	PREFILL CALC		
2.01.13C	Pharmaceutical expenditure as a % of GDP (% of GDP)	PREFILL CALC		
2.01.14C	Pharmaceutical expenditure as a % of Health Expenditure (% of total health expenditure)	PREFILL CALC		
2.01.15.01	Total public expenditure on pharmaceuticals (millions NCU)	0		

pharmaceuticals (millions US\$ current exchange rate)  2.01.16C  Share of public expenditure on pharmaceuticals as percentage of total expenditure on pharmaceuticals (%)  2.01.17.01C  Total public expenditure on pharmaceuticals (PREFILL CALC)  2.01.17.02C  Total public expenditure on pharmaceuticals per capita (US\$ current exchange rate)  2.01.18.01  Total private expenditure on pharmaceuticals (millions NCU)  2.01.18.02  Total private expenditure on pharmaceuticals (millions NCU)  2.01.18.02  Total private expenditure on pharmaceuticals (millions US\$ current exchange rate)  2.01.18.02  Total private expenditure on pharmaceuticals (millions US\$ current exchange rate)  2.01.18.02  Total private expenditure on pharmaceuticals (millions US\$ current exchange rate)  2.01.18.01  Supplementary questions (click for help)	0.04.45.00				
pharmaceuticals as percentage of total expenditure on pharmaceuticals (%)  2.01.17.01C  Total public expenditure on pharmaceuticals per capita (NCU)  2.01.17.02C  Total public expenditure on pharmaceuticals per capita (US\$ current exchange rate)  2.01.18.01  Total private expenditure on pharmaceuticals (millions NCU)  2.01.18.02  Total private expenditure on pharmaceuticals (millions NCU)  2.01.18.02  Total private expenditure on pharmaceuticals (millions US\$ current exchange rate)  2.01.18.02  Comments and References  2.01.18.01 figures are in local currency (leones). 2.01.18.02 fig are in US dollars. The Ministry of Health and Sanitation will soo conduct its second NHA surveys wherein all health care financi issues will be addressed. Period to be covered will include 200: 2009, 2010.  Supplementary questions (click for help)  Social security expenditure as % of government expenditure on health (% of government expenditure on health)  2.01.20S  Market share of generic pharmaceuticals [branded and INN] by value (%)  Annual growth rate of total pharmaceuticals market value (%)  2.01.22S  Annual growth rate of total pharmaceuticals market value (%)	2.01.15.02	1 .	0		
pharmaceuticals per capita (NCU)  2.01.17.02C  Total public expenditure on pharmaceuticals per capita (US\$ current exchange rate)  2.01.18.01  Total private expenditure on pharmaceuticals (millions NCU)  2.01.18.02  Total private expenditure on pharmaceuticals (millions US\$ current exchange rate)  2.01.19  Comments and References  2.01.18.01 figures are in local currency (leones). 2.01.18.02 fig are in US dollars. The Ministry of Health and Sanitation will soc conduct its second NHA surveys wherein all health care financi issues will be addressed. Period to be covered will include 200: 2009, 2010.  Supplementary questions (click for help)  Social security expenditure as % of government expenditure on health (% of government expenditure on health)  Arket share of generic pharmaceuticals [branded and INN] by value (%)  Annual growth rate of total pharmaceuticals market value (%)	2.01.16C	pharmaceuticals as percentage of total expenditure on pharmaceuticals	PREFILL CALC		
pharmaceuticals per capita (US\$ current exchange rate)  2.01.18.01 Total private expenditure on pharmaceuticals (millions NCU)  2.01.18.02 Total private expenditure on pharmaceuticals (millions US\$ current exchange rate)  2.01.19 Comments and References  2.01.19 Comments and References  2.01.19 Comments and References  2.01.18.01 figures are in local currency (leones). 2.01.18.02 fig are in US dollars. The Ministry of Health and Sanitation will so conduct its second NHA surveys wherein all health care financi issues will be addressed. Period to be covered will include 200: 2009, 2010.  Supplementary questions (click for help)  2.01.20S Social security expenditure as % of government expenditure on health (% of government expenditure on health)  2.01.21S Market share of generic pharmaceuticals (branded and INN) by value (%)  Annual growth rate of total pharmaceuticals market value (%)	2.01.17.01C		PREFILL CALC		
pharmaceuticals (millions NCU)  2.01.18.02 Total private expenditure on pharmaceuticals (millions US\$ current exchange rate)  2.01.19 Comments and References  2.01.18.01 figures are in local currency (leones). 2.01.18.02 fig are in US dollars. The Ministry of Health and Sanitation will so conduct its second NHA surveys wherein all health care financi issues will be addressed. Period to be covered will include 200 2009, 2010.  Supplementary questions (click for help)  2.01.20S Social security expenditure as % of government expenditure on health (% of government expenditure on health)  2.01.21S Market share of generic pharmaceuticals (branded and INN) by value (%)  2.01.22S Annual growth rate of total pharmaceuticals market value (%)	2.01.17.02C	pharmaceuticals per capita	PREFILL CALC		
pharmaceuticals (millions US\$ current exchange rate)  2.01.19 Comments and References  2.01.18.01 figures are in local currency (leones). 2.01.18.02 fig are in US dollars. The Ministry of Health and Sanitation will soo conduct its second NHA surveys wherein all health care financi issues will be addressed. Period to be covered will include 200i 2009, 2010.  Supplementary questions (click for help)  2.01.208 Social security expenditure as % of government expenditure on health (% of government expenditure on health)  2.01.218 Market share of generic pharmaceuticals [branded and INN] by value (%)  2.01.228 Annual growth rate of total pharmaceuticals market value (%)	2.01.18.01	1	91,986,619,572	2008	
are in US dollars. The Ministry of Health and Sanitation will soo conduct its second NHA surveys wherein all health care financi issues will be addressed. Period to be covered will include 200 2009, 2010.  Supplementary questions (click for help)  2.01.20S  Social security expenditure as % of government expenditure on health (% of government expenditure on health)  2.01.21S  Market share of generic pharmaceuticals [branded and INN] by value (%)  2.01.22S  Annual growth rate of total pharmaceuticals market value (%)  0	2.01.18.02	pharmaceuticals (millions US\$	21,807,670.65	2008	
2.01.20S  Social security expenditure as % of government expenditure on health (% of government expenditure on health)  2.01.21S  Market share of generic pharmaceuticals [branded and INN] by value (%)  Annual growth rate of total pharmaceuticals market value (%)  Merket share of generic of pharmaceuticals [branded and INN] by value (%)  O  2.01.22S  Annual growth rate of total pharmaceuticals market value (%)	2.01.19	Comments and References	are in US dollars. The Ministry of Health are conduct its second NHA surveys wherein a issues will be addressed. Period to be covered to the	nd Sanitatior all health car	n will soon re financing
2.01.208  Social security expenditure as % of government expenditure on health (% of government expenditure on health)  2.01.218  Market share of generic pharmaceuticals [branded and INN] by value (%)  2.01.228  Annual growth rate of total pharmaceuticals market value (%)  O  NHA  O  2008  NHA  O	Suppleme	ntary questions (click for help)			
government expenditure on health (% of government expenditure on health)  2.01.21S Market share of generic pharmaceuticals [branded and INN] by value (%)  2.01.22S Annual growth rate of total pharmaceuticals market value (%)				Year	Source
pharmaceuticals [branded and INN] by value (%)  2.01.22S  Annual growth rate of total pharmaceuticals market value (%)  0	2.01.20\$	government expenditure on health (%	0	2008	NHA
pharmaceuticals market value (%)	2.01.21S	pharmaceuticals [branded	0		
2.01.23S Annual growth rate of generic 0	2.01.22\$	pharmaceuticals market	0		
pharmaceuticals market value (%)	2.01.23\$	pharmaceuticals market	0		

2.01.24S	Private <u>out-of-pocket</u> expenditure as % of private health expenditure (% of private expenditure on health)	57.27	2008	NHA data
2.01.25S	Premiums for private prepaid health plans as % of total private health expenditure (% of private expenditure on health)	3.99	2008	NHA data
2.01.26S	Comments and References	0 means data is not available.		
2 02 Heal	th Personnel and Infrastructure			
	stions (click for help)			
			Year	Source
2.02.01	Total number of pharmacists licensed/registered to practice in your country	259	2011	Pharmacy Board
2.02.02C	Pharmacists per 10,000 population	0.03		
2.02.03	Total number of pharmacists working in the public sector	30	2011	Pharmacy Board
2.02.04	Total number of pharmaceutical technicians and assistants	441	2011	Pharmacy Board
2.02.05	A strategic plan for pharmaceutical human resource development is in place in your country?	Yes □ No ⊠		
2.02.06	Total number of physicians	95	2009	WHS
2.02.07C	Physicians per 10,000 pop	0.2		
2.02.08	Total number of <u>nursing and</u> <u>midwifery personnel</u>	1717	2010	МоН
2.02.09C	Nurses and midwives per 10,000 pop	1.78		
2.02.10	Total number of hospitals	25	2010	МоН
2.02.11	Number of hospital beds per 10,000 pop	4	2009	WHS

2.02.12	Total number of primary health care units and centers	1060	2011	МоН
2.02.13	Total number of licensed pharmacies	147	2011	Pharmacy Board
2.02.14	Comments and References			
Supplem	entary questions (click here for hel	<u>o</u> )		
			Year	Source
2.02.15S	Starting annual salary for a newly registered pharmacist in the public sector (NCU)	1,197,000	2011	Pharmacy Board
2.02.16S	Total number of pharmacists who graduated (first degree) in the past 2 years in your country	18	2010	Pharmacy Board
2.02.17\$	Are there <u>accreditation</u> requirements for pharmacy schools?	Yes ⊠ No□		
2.02.18S	Is the Pharmacy Curriculum regularly reviewed?	Yes □ No ⊠		
2.02.19S	Comments and References	Due to the initiative of WAHO to harmonise pharmacy education in West Africa from B. Pharm to D.Pharm, the curriculum has been reviewed. They key challenge to the implementation of the process is accute shortage of lecturers.		

#### **Section 3 Policy issues** 3.00 Respondent Information Section 4 3.00.01 Name of person responsible for filling Dr Edward Magbity, Directorate of out this section of the instrument Planning and Information, MoH 3.00.02 Phone number 00232 78 434 267 3.00.03 Email address magbity@gmail.com 3.00.04 Other respondents for filling out this Mariatu Challe, DPI, MoHS section 3.01 Policy Framework Core questions (click here for help) Year Source 3.01.01 Yes ⊠ No □ National Health Policy exists. If yes, please write year of the most recent document in the "year" field. 3.01.02 Yes ⊠ No □ National Health Policy Implementation plan exists. If yes, please write the year of the most recent document in the "year" 3.01.03 Please provide comments on the The health policy is outdated. The implementation plan is not Health policy and its implementation aligned with the policy plan 3.01.04 Yes ⊠ No □ WHO level National Medicines Policy official 2004 document exists. If yes, please write the year of the most recent document in the "year" field. 3.01.05 Group of policies addressing Yes ⊠ No □ pharmaceuticals exist. 3.01.06 National Medicines Policy covers the following components:

3.01.06.01	Selection of Essential Medicines	⊠Yes		
3.01.06.02	Medicines Financing	⊠Yes		
3.01.06.03	Medicines Pricing	□Yes		
3.01.06.04	Medicines Procurement	⊠Yes		
3.01.06.05	Medicines Distribution	⊠Yes		
3.01.06.06	Medicines Regulation	⊠Yes		
3.01.06.07	<u>Pharmacovigilance</u>	□Yes		
3.01.06.08	Rational Use of Medicines	⊠Yes		
3.01.06.09	Human Resource Development	∐Yes		
3.01.06.10	Research	⊠Yes		
3.01.06.11	Monitoring and Evaluation	⊠Yes		
3.01.06.12	<u>Traditional Medicine</u>	⊠Yes		
3.01.07	National medicines policy implementation plan exists. If yes, please write year of the most recent document.	Yes ⊠ No □	2004	WHO level I
3.01.08	Policy or group of policies on clinical laboratories exist. If yes, please write year of the most recent document in the "year" field	Yes ⊠ No □		
3.01.09	National clinical laboratory policy implementation plan exists. If yes, please write year of the most recent document in the "year" field	Yes ⊠ No □	2010	
3.01.10	Access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution or national legislation?	Yes □ No ⊠	2006	
3.01.11	There are official written guidelines	Yes ⊠ No □	2007	WHO level

	on medicines donations.			I
3.01.12	Is pharmaceutical policy implementation being regularly monitored/assessed?	Yes □ No ⊠		
3.01.12.01	Who is responsible for pharmaceutical policy monitoring?	Directorate of Drugs and Medical Supplies Sanitation	, Ministry of	Health and
3.01.13	Is there a national good governance policy?	Yes ☐ No ⊠		
3.01.13.01	Multisectoral	□Yes		
3.01.13.02	For the pharmaceutical sector	□Yes		
3.01.13.03	Which agencies are responsible?			
3.01.14	A policy is in place to manage and sanction conflict of interest issues in pharmaceutical affairs.	Yes ☐ No ⊠		
3.01.15	There is a formal code of conduct for public officials.	Yes ⊠ No □		
3.01.16	Is there a whistle-blowing mechanism allowing individuals to raise a concern about wrongdoing occurring in the pharmaceutical sector of your country (ombudsperson)?	Yes ⊠ No □		
3.01.16.01	Please describe:	There is the Anti-Corruption Commision an Ombudsman	d Office of t	ne
3.01.17	Comments and References			

#### Section 4 Medicines Trade and Production 4.00 Respondent Information Section 4 4.00.01 Mr Wilshire Johnson, Registrar, Pharmacy Board of Sierra Leone Name of person responsible for filling out this section of the instrument 4.00.02 Phone number 00232 22 229346, 228497, 228351, 224526 4.00.03 Email address pharmbdsl@hotmail.com 4.00.04 Other respondents for filling out this Mrs Grace Macauley, Ministry of Trade and Industry. Freetown. section Sierra Leone, 00232 76 535290 4.01 Intellectual Property Laws and Medicines Core questions (click here for help) Year Source 4.01.01 Yes ⊠ No□ Country is a member of the World 1995 **WTO** Trade Organization 2007 WHO level 4.01.02 Legal provisions provide for granting of Patents on: 4.01.02.01 Yes ⊠ No□ Pharmaceuticals 4.01.02.02 Yes No No Laboratory supplies 4.01.02.03 Medical supplies Yes \quad No \quad \quad 4.01.02.04 Yes No No Medical equipment 4.01.03.01 Please provide name and address of As at now the Office of Administrator and Registrar General the institution responsible for manages patent and other things; whilst copy rights are managed managing and enforcing intellectual at the Ministry of Tourism and Cultural Affairs. property rights 4.01.03.02 Please provide **URL** 4.01.04 Yes ☐ No ☒ National Legislation has been 2007 WHO level modified to implement the TRIPS Agreement 4.01.05 Yes ☐ No⊠ Current laws contain (TRIPS) flexibilities and safeguards

4.01.06	Country is eligible for the transitional period to 2016	Yes ⊠ No□	2010	WTO
4.01.07	Which of the following (TRIPS) flexibilities and safeguards are present in the national law?		2007	WHO level
4.01.07.01	Compulsory licensing provisions that can be applied for reasons of public health	Yes ⊠ No □		
4.01.07.02	Bolar exception	Yes ☐ No ⊠		
4.01.08	Are <u>parallel importing</u> provisions present in the national law?	Yes □ No ⊠	2007	
4.01.09	The country is engaged in initiatives to strengthen capacity to manage and apply intellectual property rights to contribute to innovation and promote public health	Yes ⊠ No □		
4.01.10	Are there legal provisions for data exclusivity for pharmaceuticals	Yes □ No ⊠		
4.01.11	Legal provisions exist for <u>patent</u> extension	Yes □ No ⊠		
4.01.12	Legal provisions exist for linkage between patent status and Marketing Authorization	Yes □ No ⊠		
4.01.13	Comments and References			
4.02 Manu	facturing		_	
	ions ( <mark>click here for help</mark> )			
			Year	Source
4.02.01	Number of licensed pharmaceutical manufacturers in the country	None		
4.02.02	Country has manufacturing capacity		2007	WHO level
4.02.02.01	R&D to discover new active	Yes ☐ No ☑ Unknown ☐		

	substances			
4.02.02.02	Production of pharmaceutical starting materials (APIs)	Yes ⊠ No □ Unknown □		
4.02.02.03	Production of formulations from pharmaceutical starting material	Yes ☐ No ⊠ Unknown ☐		
4.02.02.04	Repackaging of finished dosage forms	Yes ⊠ No ☐ Unknown ☐		
4.02.03	Percentage of market share by value produced by domestic manufacturers (%)			
4.02.04	Comments and References	No domestic manufacturer available as at lecensed manufactureers there is none lice However, one is about to be licensed.		•
Suppleme	ntary questions (click here for help	2)		
			Year	Source
4.02.05\$	Percentage of market share by volume produced by domestic manufacturers (%)			
4.02.06S	Number of multinational pharmaceutical companies manufacturing medicines locally			
4.02.07S	Number of manufacturers that are  Good Manufacturing Practice (GMP) certified			
4.02.08S	Comments and References	No domestic manufacturers available in the	e country.	

#### **Section 5 Medicines Regulation** 5.00 Respondent Information Section 4 5.00.01 Name of person responsible for filling Mr Wilshire Johnson, Registrar, PHARMACY BOARD OF SIERRA **LEONE** out this section of the instrument 5.00.02 Phone number 00 232 22 229346, 228497, 228351, 224526 5.00.03 Email address pharmbdsl@hotmail.com 5.00.04 Other respondents for filling out this ALL HEADS OF DEPARTMENTS OF PHARMACY BOARD section **5.01 Regulatory Framework** Core questions (click here for help) Year Source Yes ⊠ No □ 5.01.01 Are there legal provisions 2007 WHO level establishing the powers and responsibilities of the Medicines Regulatory Authority (MRA)? 5.01.02 There is a Medicines Regulatory Yes ⊠ No □ WHO level 2007 Authority 5.01.03 If yes, please provide name and PHARMACY BOARD OF SIERRA LEONE address of the Medicines regulatory **CENTRAL MEDICAL STORES** authority **NEW ENGLAND VILLE FREETOWN** 5.01.04 The Medicines Regulatory Authority ⊠Yes 5.01.04.01 Part of MoH ⊠Yes 5.01.04.02 Semi autonomous agency

5.01.04.03	Other (please specify)		
5.01.05	What are the functions of the National Medicines Regulatory Authority?		
5.01.05.01	Marketing authorization / registration	Yes ⊠ No □	
5.01.05.02	Inspection	Yes ⊠ No □	
5.01.05.03	Import control	Yes ⊠ No □	
5.01.05.04	Licensing	Yes ⊠ No □	
5.01.05.05	Market control	Yes ⊠ No □	
5.01.05.06	Quality control	Yes ⊠ No □	
5.01.05.07	Medicines advertising and promotion	Yes ⊠ No □	
5.01.05.08	Clinical trials control	Yes ⊠ No □	
5.01.05.09	<u>Pharmacovigilance</u>	Yes ⊠ No □	
5.01.05.10	Other: (please explain)		
5.01.06	Number of the MRA permanent staff	107	
5.01.06.01	Date of response		
5.01.07	The MRA has its own website	Yes ⊠ No □	
5.01.07.01	- If yes, please provide MRA Web site address (URL)	www.pharmacyboard.gov.sl	
5.01.08	The MRA receives external technical assistance	Yes ⊠ No □	
5.01.08.01	If yes, please describe:		
5.01.09	The MRA is involved in harmonization/ collaboration initiatives	Yes ⊠ No □	2007 WHO level
5.01.09.01	- If yes, please specify	West Africa Health Organization (WA Regulatory Authority, Roll Back Malar	_

5.01.10	An assessment of the medicines regulatory system has been conducted in the last five years.	Yes ⊠ No □			
5.01.11	Medicines Regulatory Authority gets funds from regular budget of the government.	Yes ⊠ No □	2007	WHO level	
5.01.12	Medicines Regulatory Authority is funded from fees for services provided.	Yes ☐ No ⊠	2007	WHO level I	
5.01.13	Medicines Regulatory Authority receives funds/support from other sources	Yes ⊠ No □	2007	WHO level	
5.01.13.01	- If yes, please specify				
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 □			
5.01.16	Comments and References	Only registration and importation information are computerized. All funds generated are paid directly into the consolidated fund (escrow account). Only clinical trials data are analysed in medicines dossier. Proposal for training intoxicity studies and clinical trials is being prepared at the moment.			
5.02 Marke	eting Authorization (Registration)				
	ions ( <u>click here for help</u> )				
			Year	Source	
5.02.01	Legal provisions require a Marketing Authorization (registration) for all pharmaceutical products on the market	Yes ⊠ No □	2007	WHO level	

		•		
5.02.02	Are there any mechanism for exception/waiver of registration?	Yes ⊠ No □		
5.02.03	Are there mechanisms for recognition of registration done by other countries	Yes ⊠ No □		
5.02.03.01	If yes, please explain:	Memorandum of understanding with Food	and Drugs E	Board, Ghana
5.02.04	Explicit and publicly available criteria exist for assessing applications for Marketing Authorization of pharmaceutical products	Yes ⊠ No □		
5.02.05	Information from the <u>prequalification</u> programme managed by WHO is used for product registration	Yes ⊠ No □		
5.02.06	Number of pharmaceutical products registered in your country	590 registered, 1700 pending		
5.02.07	Legal provisions require the MRA to make the list of registered pharmaceuticals with defined periodicity publicly available	Yes ⊠ No □	2007	WHO level
5.02.07.01	If yes, how frequently updated	Yearly		
5.02.07.02	If yes, please provide updated list or URL *	We keep a register open to the public at al	l times.	
5.02.08	Medicines registration always includes the INN (International Non-proprietary Names)	Yes ⊠ No □	2007	WHO level
5.02.09	Legal provisions require the payment of a fee for Medicines Marketing Authorization (registration) applications	Yes ⊠ No □	2001	
5.02.10	Comments and References			
Supplemen	ntary questions ( <u>click here for help</u>	2)		
			Year	Source
5.02.11S	Legal provisions require Marketing Authorization holders to provide	Yes ⊠ No □	2001	

		1	T	<del>-</del>	
	information about variations to the existing Marketing Authorization				
5.02.12S	Legal provisions require publication of a Summary of Product Characteristics (SPCs) of the medicines registered	Yes ⊠ No □	2001		
5.02.13\$	Legal provisions require the establishment of an expert committee involved in the marketing authorization process	Yes ⊠ No □	2007	WHO level 1	
5.02.148	Certificate for Pharmaceutical Products in accordance with the WHO Certification scheme is required as part of the Marketing Authorization application	Yes ⊠ No □	2007	WHO level	
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 ⊠			
5.02.16S	Legal provisions allow applicants to appeal against MRAs decisions	Yes ⊠ No □			
5.02.17S	Registration fee - the amount per application for pharmaceutical product containing New Chemical Entity (NCE) (US\$)	US\$720			
5.02.18S	Registration fee - the Amount per application for a generic pharmaceutical product (US\$)	US\$250			
5.02.19S	Time limit for the assessment of a Marketing Authorization application (months)	3 MONTHS			
5.02.20S	Comments & References				
5 02 Dogg	latony Inchestion				
	latory Inspection				
Core Ques	Core Questions(clickhere for help)				

		Year	Source
Legal provisions exist allowing f appointment of government pharmaceutical inspectors	or Yes ⊠ No □		
5.03.02 Legal provisions exist permitting inspectors to inspect premises of pharmaceutical activities are performed		2007	WHO level I
5.03.02.01 If yes, legal provisions exist req inspections to be performed	uiring Yes ⊠ No □		
5.03.03 Inspection is a pre-requisite for licensing of:			
5.03.03.01 Public facilities	Yes □ No ⊠		
5.03.03.02 Private facilities	Yes ⊠ No □		
Inspection requirements are the same for public and private facilities	Yes ⊠ No □		
5.03.05.01 Local manufactures are inspect GMP compliance	ed for Yes ⊠ No □	2007	WHO level
5.03.05.02 Private <u>wholesalers</u> are inspect	ed Yes⊠ No 🗌		
5.03.05.03 <u>Retail distributors</u> are inspected	Yes ⊠ No □		
5.03.05.04 Public pharmacies and stores a inspected	re Yes ⊠ No □		
5.03.05.05 Pharmacies and dispensing poi health facilities are inspected	nts of Yes ⊠ No □		
5.03.05.06 Please provide details on freque of inspections for the different categories of facilities	ency AT LEAST ONCE EVERY QUARTER		
5.03.06 Comments and References			
5.04 Import Control			
Core Questions ( <u>click here for help</u> )			

•			F	
			Year	Source
5.04.01	Legal provisions exist requiring authorization to import medicines	Yes ⊠ No □		
5.04.02	Legal provisions exist allowing the sampling of imported products for testing	Yes ⊠ No □		
5.04.03	Legal provisions exist requiring importation of medicines through authorized ports of entry	Yes ⊠ No □		
5.04.04	Legal provisions exist allowing inspection of imported pharmaceutical products at the authorized ports of entry	Yes ⊠ No □		
5.04.05	Comments and References			
5.05 Licen	sing			
			Year	Source
5.05.01	Legal provisions exist requiring manufacturers to be licensed	Yes ⊠ No □	2007	WHO level
5.05.02	Legal provisions exist requiring both domestic and international manufacturers to comply with Good manufacturing Practices (GMP)	Yes ⊠ No □		
5.05.02.01	If no, please explain			
5.05.03	GMP requirements are published by the government.	Yes ⊠ No □		
5.05.04	Legal provisions exist requiring importers to be licensed	Yes ⊠ No □	2007	WHO level
5.05.05	Legal provisions exist requiring wholesalers and distributors to be licensed	Yes ⊠ No □	2007	WHO level
5.05.06	Legal provisions exist requiring wholesalers and distributors to comply with Good Distributing Practices	Yes ⊠ No □		

	When filling in this part, please			
	also fill in the relevant questions in			
	the procurement and distribution			
	section (Section 7)			
5.05.07	National Good Distribution Practice	Yes ⊠ No □		
	requirements are published by the			
	government			
5.05.08	Legal provisions exist requiring	Yes ⊠ No □		
0.00.00	pharmacists to be registered			
	priarriadists to be registered			
5.05.09	Legal provisions exists requiring	Yes ⊠ No □		
	private pharmacies to be licensed			
5.05.10	Legal provision exist requiring public	Yes ☐ No ⊠		
	pharmacies to be licensed			
5.05.11	National Good Pharmacy Practice	Yes ☐ No ⊠		
	Guidelines are published by the			
	government			
5.05.12	Legal provisions require the	Yes ⊠ No □		
	publication of a list of all licensed			
	pharmaceutical facilities			
5.05.13	Comments and References			
F 06 Morle	at Control and Quality Control			
5.00 Marke	et Control and Quality Control			
Core Quest	ions ( <u>click here for help</u> )			
			Year	Source
5.06.01	Legal Provisions for regulating the	Yes ⊠ No □		
	pharmaceutical market exist			
5.06.02	Door a laboratory aviatin the accepture	Vac M Na 🗆		
0.00.02	Does a laboratory exist in the country for Quality Control testing?	Yes ⊠ No □		
	ior Quality Control testing?			
5.06.02.01	If yes, is the laboratory part of the	Yes ⊠ No □		
	MRA?			
5.06.02.02	Does the regulatory authority contract	Yes ⊠ No □		
	services elsewhere?			
5.06.02.03	If yes, please describe			

5.06.03	Is there any national laboratory accepted for collaboration with WHO prequalification Programme? Please describe.	NO		
5.06.04	Medicines are tested:			
5.06.04.01	For quality monitoring in the public sector (routine sampling in pharmacy stores and health facilities)	Yes ⊠ No □		
5.06.04.02	For quality monitoring in private sector (routine sampling in retail outlets)	Yes ⊠ No □		
5.06.04.03	When there are complaints or problem reports	Yes ⊠ No □		
5.06.04.04	For product registration	Yes ⊠ No □		
5.06.04.05	For public procurement prequalification	Yes □ No ⊠		
5.06.04.06	For public program products prior to acceptance and/or distribution	Yes ⊠ No □		
5.06.05	Samples are collected by government inspectors for undertaking post-marketing surveillance testing	Yes ⊠ No □	2007	WHO level
5.06.06	How many Quality Control samples were taken for testing in the last two years?	957		
5.06.07	Total number of samples tested in the last two years that failed to meet quality standards	26		
5.06.08	Results of quality testing in past two years are publicly available	Yes ⊠ No □		
5.06.09	Comments and References	Results on quality testing are available on	request.	

#### **5.07 Medicines Advertising and Promotion Core Questions (click here for help)** Year Source 5.07.01 Yes ⊠ No □ WHO level Legal provisions exist to control the 2007 promotion and/or advertising of prescription medicines 5.07.02 Who is responsible for regulating, PHARMACY BOARD OF SIERRA LEONE promotion and/or advertising of medicines? Please describe: 5.07.03 Legal provisions prohibit direct Yes ⊠ No □ WHO level 2007 advertising of prescription medicines Τ to the public 5.07.04 Yes ⊠ No □ Legal provisions require a pre-2007 WHO level approval for medicines advertisements and promotional materials 5.07.05 Yes ⊠ No □ WHO level Guidelines/Regulations exist for 2007 advertising and promotion of nonprescription medicines 5.07.06 Yes ⊠ No □ A national code of conduct exists concerning advertising and promotion of medicines by marketing authorization holders and is publicly available 5.07.06.01 If yes, the code of conduct applies to domestic manufacturers only, multinational manufacturers only, or both ⊠Yes Domestic only □Yes Multinational only □Yes Both 5.07.06.02 Yes ☐ No 🖂 If yes, adherence to the code is voluntary

5.07.06.03	If yes, the code contains a formal process for complaints and sanctions	Yes ⊠ No □		
5.07.06.04	If yes, list of complaints and sanctions for the last two years is publicly available	Yes □ No ⊠		
5.07.07	Comments and References	Interested parties can visit the Pharmacy E complaints and sanctions.	Board for info	ormation on
5.08 Clinica	al trials ions (click here for help)			
core quest				
			Year	Source
5.08.01	Legal provisions exist requiring authorization for conducting Clinical Trials by the MRA	Yes □ No ⊠		
5.08.02	Legal provisions exist requiring the agreement by an ethics committee/ institutional review board of the Clinical Trials to be performed	Yes □ No ⊠		
5.08.03	Legal provisions exist requiring registration of the clinical trials into international/national/regional registry	Yes □ No ⊠		
5.08.04	Comments and References			
Supplementary	y questions ( <u>click here for help</u> )			
			Year	Source
5.08.05S	Legal provisions exist for GMP compliance of investigational products	Yes □ No ⊠		
5.08.06\$	Legal provisions require sponsor, investigator to comply with Good Clinical Practices (GCP)	Yes □ No ⊠		
5.08.07\$	National GCP regulations are published by the Government.	Yes □ No ⊠		
5.08.08\$	Legal provisions permit inspection of	Yes ☐ No ⊠		

	facilities where clinical trials are performed			
5.08.09S	Comments and References	THE PHARMACY AND DRUGS ACTS 20 BEING REVIEWED AND REVISED.	01 IS CURR	ENTLY
5.09 Contr	olled Medicines			
Core Quest	tions (click here for help)			
			Date	Source
5.09.01	The country has adopted the following conventions:			
5.09.01.01	Single Convention on Narcotic Drugs, 1961	Yes ⊠ No □		
5.09.01.02	The 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	Yes ⊠ No □	1994	Internation al Narcotics Control Board, 2010
5.09.01.03	Convention on Psychotropic Substances 1971	Yes ⊠ No □	1994	Internation al Narcotics Control Board, 2010
5.09.01.04	United Nations <u>Convention against</u> the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	Yes ⊠ No □	1989	Internation al Narcotics Control Board, 2010
5.09.02	Laws for the control of narcotic and psychotropic substances, and precursors exist	Yes ⊠ No □		
5.09.03	Annual consumption of Morphine (mg/capita)	0.011871	2009	Internation al Narcotics Control Board, 2010
5.09.04	Comments and References			

Supplemen	ntary questions ( <u>click here for help</u>	2)		
			Year	Source
5.09.05S	The legal provisions and regulations for the control of narcotic and psychotropic substances, and precursors have been reviewed by a WHO International Expert or Partner Organization to assess the balance between the prevention of abuse and access for medical need	Yes ⊠ No □ Unknown □		
5.09.05.01S	If yes, year of review			
5.09.06\$	Annual consumption of Fentanyl (mg/capita)	0.557960 1 gram	2009	Internation al Narcotics Control Board, 2010
5.09.07S	Annual consumption of Pethidine (mg/capita)	0.004137 10,000 gram	2009	Internation al Narcotics Control Board, 2010
5.09.08\$	Annual consumption of Oxycodone (mg/capita)	Not included in our estimates		
5.09.09S	Annual consumption of Hydrocodone (mg/capita)	Not included in our estimates		
5.09.10S	Annual consumption of Phenobarbital (mg/capita)	51,000 gram		
5.09.11S	Annual consumption of Methadone (mg/capita)	Not included in our estimates		
5.09.12S	Comments and References			
5.10 Pharm	nacovigilance			
Core Quest	ions (click here for help)			
			Year	Source
5.10.01	There are legal provision in the Medicines Act that provides for	Yes □ No ⊠		

	pharmacovigilance activities as part of the MRA mandate		
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	Five (5) staff	
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?	1,000	
5.10.08	How many reports have been submitted in the last two years?	768 (June 2009 -June 2011)	
5.10.09	Are ADR reports sent to the WHO database in Uppsala?	Yes ⊠ No □	
5.10.09.01	If yes, number of reports sent	333	

	in the last two years			
5.10.10	Is there a national ADR or pharmacovigilance advisory committee able to provide technical assistance on causality assessment, risk assessment, risk management, case investigation and, where necessary, crisis management including crisis communication?	Yes ⊠ No □		
5.10.11	Is there a clear communication strategy for routine communication and crises communication?	Yes ⊠ No □		
5.10.12	In the absence of a national pharmacovigilance system, ADRs are monitored in at least one public health program (for example TB, HIV, AIDS)?	Yes ⊠ No □		
5.10.13	Please describe how you intend to enhance the Pharmacovigilance system	The setting up of institutional focal points in the various public health programs and facilities and also making the reporting on ADRs mandatory in the current review of the ACT.		
5.10.14	Comments and References	With regards to question 5.10.04.3, a newslett	ter is regularly	y produced.
Suppleme	ntary questions ( <u>click here for help</u>	<u>)</u>		
			Year	Source
5.10.15S	Feedback is provided to reporters	Yes ⊠ No □		
5.10.16S	The ADR database is computerized	Yes ⊠ No □		
5.10.17S	Medication errors (MEs) are reported	Yes ⊠ No □		
5.10.18\$	How many MEs are there in the ADRs database?	5		
5.10.19\$	There is a <u>risk management plan</u> presented as part of product dossier submitted for Marketing Authorization?	Yes ⊠ No □		
5.10.20S	In the past two years, who has reported ADRs?			

5.10.20.01S	Doctors	⊠Yes		
5.10.20.02S	Nurses	⊠Yes		
5.10.20.03\$	Pharmacists	⊠Yes		
5.10.20.04S	Consumers	⊠Yes		
5.10.20.05S	Pharmaceutical Companies	⊠Yes		
5.10.20.06S	Others, please specify whom	Local companies report copies of their pro-	ducts.	
5.10.21\$	Was there any regulatory decision based on local pharmacovigilance data in the last 2 years?	Yes ⊠ No□		
5.10.22S	Are there training courses in pharmacovigilance?	Yes ⊠ No□		
5.10.22.01S	If yes, how many people have been trained in the last two years?	250hth		
5.10.23S	Comments and References	With regards to question 5.10.19S, it is only for new product entities. For question 5.10.22S, the Pharmacy Board has been conducting trainings on PVG for various health care providers.		

#### **Section 6 Medicines Financing** 6.00 Respondent Information Section 5 6.00.01 Name of person responsible for filling Mr Dennis Thomas, Directorate of Drugs and Medical Supplies, out this section of the instrument Ministry of Health and Sanitation 6.00.02 Phone number 00 232 76 606367 6.00.03 Email address denntamba@yahoo.com 6.00.04 Other respondents for this sections Mr Bassie Turay, Director Medicines and Medical Supplies, MOH **6.01 Medicines Coverage and Exemptions Core Questions (click here for help)** Source Year 2007 WHO level 6.01.01 Do the followings receive medicines free of charge: Yes ⊠ No□ 6.01.01.01 Patients who cannot afford them 6.01.01.02 Yes ⊠ No□ Children under 5 6.01.01.03 Yes ⊠ No□ Pregnant women 6.01.01.04 Yes ⊠ No□ Elderly persons 6.01.01.05 Please describe/explain your yes There are government policies to treat all the above categories of answers for questions above people free of cost 2007 WHO level 6.01.02 Is there a public health system or social health insurance scheme or public programme providing medicines free of charge for: 6.01.02.01 All medicines included in the EML Yes ☐ No 🖂 6.01.02.02 Yes ☐ No 🖂 Any non-communicable diseases 6.01.02.03 Malaria medicines Yes ⊠ No □ 6.01.02.04 Yes ⊠ No □ Tuberculosis medicines 6.01.02.05 Yes ⊠ No □ Sexually transmitted diseases

	medicines			
6.01.02.06	HIV/AIDS medicines	Yes ⊠ No □		
6.01.02.07	Expanded Program on Immunization (EPI) vaccines	Yes ⊠ No □		
6.01.02.08	If others, please specify			
6.01.02.09	Please describe/explain your yes answers for questions above	Global Fund provides funds for the treatmest specific areas	ent of the ab	ov e disease
6.01.03	Does a national health insurance, social insurance or other <u>sickness</u> <u>fund</u> provide at least partial <u>medicines</u> <u>coverage</u> ?	Yes ☐ No ⊠		
6.01.03.01	Does it provide coverage for medicines that are on the EML for inpatients	Yes □ No ⊠		
6.01.03.02	Does it provide coverage for medicines that are on the EML for outpatients	Yes ☐ No ⊠		
6.01.03.03	Please describe the medicines benefit of public/social insurance schemes			
6.01.04	Do private health insurance schemes provide any medicines coverage?	Yes ☐ No ⊠		
6.01.04.01	If yes, is it required to provide coverage for medicines that are on the EML?	Yes ☐ No ⊠		
6.01.05	Comments and References			
6.02 Patier	nts Fees and Copayments			
Core Quest	ions (click here for help)			
			Year	Source
6.02.01	In your health system, at the point of delivery, are there any co-payment/fee requirements for consultations	Yes ⊠ No □	2007	WHO level

6.02.02	In your health system, at the point of delivery, are there any co- payment/fee requirements for medicines	Yes ⊠ No □		
6.02.03	In practice, (even though this may be contrary to regulations) is revenue from fees or sales of medicines sometimes used to pay the salaries or supplement the income of public health personnel in the same facility?	Yes ☐ No ⊠	2007	WHO level
6.02.03.01	Please describe the patient fees and copayments system	A cost recovery system which is meant for members that can afford to pay.	only those o	community
6.02.04	Comments and References	Ref: Revised Health Services Cost Recove Sierra Leone, MoHS 2006	ery Policy Gu	uidelines for
6.03 Pricin	g Regulation for the Private Sector			
Core Quest	ions ( <u>click here for help</u> )			
			Year	Source
6.03.01	Are there legal or regulatory provisions affecting pricing of medicines	Yes ⊠ No □	2007	WHO level I
6.03.01.01	If yes, are the provisions aimed at Manufacturers	Yes ☐ No ☒		
6.03.01.02	If yes, are the provisions aimed at Wholesalers	Yes □ No ⊠		
6.03.01.03	If yes, are the provisions aimed at Retailers	Yes ⊠ No □		
6.03.01.04	Please explain the positive answers above: (explain scope of provisions i.e generics vs. originator or subsets of medicines, EML etc.)	The retail of medicines in the public health facilities is regulated by government policy. The medicines are procured by government and sold on cost recovery basis at the public facilities.		
6.03.02	Government runs an active national medicines price monitoring system for retail prices	Yes ⊠ No □	2007	WHO level I
	ioi retaii prices			

	should be publicly a	accessible						
6.03.03.01	-if yes, please explainformation is made available			The price lists a points.	re posted on th	he notice boa	ard at the se	rvice delivery
6.03.04	Comments and Ref	erences		Ref: Revised He Sierra Leone, M		Cost Recove	ery Policy Gu	uidelines for
6.04 Prices	, Availability and A	Affordabili	ty					
Core Quest	ions ( <u>click here fo</u>	r help)						
							Year	Source
6.04.01-04	Please state if a me survey using the W methodology has be the past 5 years in  If yes, please indice survey and use the table  If no, but other surprices and available conducted, please fill in this section, be comment box to we results and attach to questionnaire	HO/HAI been conduct your country cate the yea e results to file veys on med lity have beed do not use to the trather use rite some of	ted in y. r of the II in this dicines en hem to e the the	Yes □ No □ I	Unknown 📋			
	Basket Of ke	ey medicin	es	Public procurement	Public patient	Private patient		
	Availability (one or both of)	Mean (%)	Orig		6.04.01.01	6.04.01.03		
			LPG		6.04.01.02	6.04.01.04		
		Median (%)	Orig		6.04.02.01	6.04.02.03		
			LPG		6.04.02.02	6.04.02.04		

	Price	Median Price Ratio	Orig	6.04.03.01	6.04.03.03	6.04.03.05		
			LPG	6.04.03.02	6.04.03.04	6.04.03.06		
	Affordability  Days' wages of the lowest paid govt worker	Number of days' wages	Orig		6.04.04.01	6.04.04.03		
	for standard treatment with co-trimoxazole for a child respiratory infection		LPG		6.04.04.02	6.04.04.04		
6.04.05	Comments and Ref	erences		Data on the ab conducted	ove questions	do not exist	as no surve	y has been
6.05 Price	Components and A	ffordabilit	y					
Core Ques	tions ( <mark>click here fo</mark>	r help)						
							Year	Source
6.05.01	Diagon state if a gui	nuov of modi	oinos	Yes No No	Inknown 🗆		rear	Source
0.00.01	Please state if a survey of medicines price components has been conducted in the past 5 years in your country			res [] NO [] (	JIIKHOWH [_]			
6.05.02	Median cumulative percentage mark- up between Manufacturer Selling Price (MSP)/ Cost Insurance and Freight (CIF) price and final medicine price for a basket of key medicines in the public sector (Median % contribution)							
6.05.03	Median cumulative percentage mark- up between MSP/CIF price and final medicine price for a basket of key medicines in the private sector (Median % contribution)							
6.05.04	Comment and Refe	No survey of p	rice medicines	components	s has been o	conducted.		
Suppleme	ntary questions (o	lick here f	or help	)				

6.05.05\$	Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the public sector (Median % contribution)	Data not available			
6.05.06S	Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the private sector (Median % contribution)	Data not available			
6.05.07\$	Median manufacturer selling price (CIF) as percent of final medicine price for a basket of key medicines (%)	Data not available			
6.05.08\$	Median wholesaler selling price as percent of final medicine price for a basket of key medicines (%)	Data not available			
6.05.09\$	Median pharmacist mark-up or dispensing fee as percent of retail price for a basket of key medicines (%)	Data not available			
6.05.10S	Median percentage contribution of the wholesale mark-up to final medicine price for a basket of key medicines (in the public and private sectors) (%)	Data not available			
6.05.11S	Median percentage contribution of the retail mark-up to final medicine price for a basket of key medicines (in the public and private sectors) (%)	Data not available			
6.05.12S	Comment and References	No assessment or survey conducted to inform on the above questions.			
1015					
6.06 Duties	s and Taxes on Pharmaceuticals (Ma	rket)			
Core Quest	cions (click here for help)				
			Year	Source	
6.06.01	There are <u>duties</u> on imported <u>active</u> <u>pharmaceutical ingredients (APIs)</u>	Yes ⊠ No □			
6.06.02	There are duties on imported finished	Yes ⊠ No □			

	products			
6.06.03	VAT (value-added tax) or any other tax is levied on finished pharmaceuticals products	Yes ⊠ No □		
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 exemptions and waivers that exist	Taxation applies to all categories of phare	maceuticals.	
6.06.06	Comments and References			
Suppleme	entary questions ( <u>click here for help</u>	)		
			Year	Source
6.06.07S	Duty on imported active pharmaceutical ingredients, APIs (%)	13.99	2011	Pharmacy Board
6.06.08S	Duty on imported finished products (%)	13.99	2011	Pharmacy Board
6.06.09S	VAT on pharmaceutical products (%)	15	2011	Pharmacy Board
6.06.10S	Comments and References		,	,

### Section 7 Pharmaceutical procurement and distribution 7.00 Respondent Information Section 6 7.00.01 Name of person responsible for Dennis Thomas, Directorate of Drugs and Medical Supplies, Ministry filling out this section of the of Health and Sanitation. instrument 7.00.02 Phone number 00 232 76 606367 7.00.03 Email address denntamba@yahoo.com 7.00.04 Other respondents for filling out this Mr Wilshire Johnson, Registrar, Pharmacy Board of Sierra Leone; Mr section Mohamed I Kallon, Procurement Manager, Ministry of Health and Sanitation. 7.01 Public Sector Procurement **Core Questions (click here for help)** Date Source 7.01.01 Public sector procurement is: ☐Yes 7.01.01.01 Decentralized ⊠Yes 7.01.01.02 Centralized and decentralized 7.01.01.03 Please describe Procurement of essential medicines is decentralised. Procurement of disease specific areas like malaria, TB and HIV/AIDS is centralized. 7.01.02 If public sector procurement is wholly or partially centralized, it is under the responsibility of a procurement agency which Yes ⊠ No □ 7.01.02.01 Part of MoH 7.01.02.02 Yes No No Semi-Autonomous

7.01.02.03	Autonomous	Yes 🗌 No 🗌		
7.01.02.04	A government procurement agency which procures all public goods	Yes ⊠ No □		
7.01.03	Public sector requests for tender documents are publicly available	Yes ⊠ No □		
7.01.04	Public sector tender awards are publicly available	Yes ⊠ No □		
7.01.05	Procurement is based on prequalification of suppliers	Yes ⊠ No □		
7.01.05.01	If yes, please describe how it works	Prequalification of suppliers is to check the s This is applicable only to large volume procu usually requested for an expression of intere government hives out credible contractors.	rement. Cor	ntractors are
7.01.06	Comments and References	On questionnaire 7.01.02.02 the governmen National Pharmaceutical Procurement Unit for products soon and it will be semi-autonomou	or pharmace	_
Suppleme	ntary questions ( <u>click here for he</u>	<mark>elp</mark> )		
			Year	Source
7.01.07\$	Is there a written public sector procurement policy?. If yes, please write the year of approval in the	Yes ⊠ No □	2004	Ministry of Health
	"year" field			procureme nt Unit
7.01.08\$		Yes □ No ⊠		procureme
7.01.08S 7.01.09S	"year" field  Are there legal provisions giving priority in public procurement to goods produced by local	Yes □ No □	2007	procureme
	"year" field  Are there legal provisions giving priority in public procurement to goods produced by local manufacturers?  The key functions of the procurement unit and those of the tender committee are clearly		2007	procureme nt Unit

7.01.10.02S	If yes, explicit criteria and procedures exist for prequalification of suppliers	Yes ⊠ No □		
7.01.10.03S	If yes, a list of pre-qualified suppliers and products is publicly available	Yes □ No ⊠		
7.01.11S	List of samples tested during the procurement process and results of quality testing are available	Yes ⊠ No □		
7.01.128	Which of the following tender methods are used in public sector procurement:		2007	WHO level
7.01.12.01S	National competitive tenders	Yes ⊠ No □		
7.01.12.028	International competitive tenders	Yes ⊠ No □		
7.01.12.03\$	Direct purchasing	Yes ⊠ No □		
7.01.13S	Comments and References	On question 7.01.12.03S, direct purchasing threshold. It is usually done for small items.	depends on	the
		threshold. It is usually done for small items.		
7.02 Public	: Sector Distribution	threshold. It is usually done for small items.		
	Sector Distribution ions (click here for help)	threshold. It is usually done for small items.		
Core Quest	ions (click here for help)		Year	Source
		Yes No	Year	Source
Core Quest	The government supply system department has a Central Medical		Year	Source
7.02.01	The government supply system department has a Central Medical Store at National Level  Number of public warehouses in the secondary tier of public distribution	Yes ⊠ No □	Year	Source

7.02.04.01	If a licensing authority exists, does it accredit public distribution facilities?	Yes □ No ⊠		
7.02.05	List of GDP certified warehouses in the public sector exists	Yes ⊠ No □		
7.02.06	List of GDP certified distributors in the public sector exists	Yes ⊠ No □		
7.02.07	Comments and References	Question 7.02.03: National guidelines on GE Unicef is involved in the distribution process distributors include Unicef and transport com	The main c	•
Suppleme	entary questions ( <u>click here for he</u>	elp)		
			Year	Source
7.02.08S	Which of the following processes is in place at the Central Medical Store:			
7.02.08.01S	Forecasting of order quantities	Yes ⊠ No □		
7.02.08.02S	Requisition/Stock orders	Yes ⊠ No □		
7.02.08.03S	Preparation of picking/packing slips	Yes ⊠ No □		
7.02.08.04S	Reports of stock on hand	Yes ⊠ No □		
7.02.08.05S	Reports of outstanding order lines	Yes ⊠ No □		
7.02.08.06S	Expiry dates management	Yes ⊠ No □		
7.02.08.07S	Batch tracking	Yes ⊠ No □		
7.02.08.08S	Reports of products out of stock	Yes ⊠ No □		
7.02.09\$	Percentage % availability of key medicines at the Central Medical Store			
7.02.10\$	Average stock-out duration for a basket of medicines at the Central Medical Store, in days	30		,
7.02.11S	Routine Procedure exists to track the expiry dates of medicines at the	Yes ⊠ No □		

	Central Medical Store			
7.02.12S	The Public Central Medical Store is GDP certified by a licensing authority	Yes ⊠ No □		
7.02.13\$	The Public Central Medical Store is ISO certified	Yes ⊠ No □		
7.02.14S	The second tier public warehouses are GDP certified by a licensing authority	Yes ⊠ No □		
7.02.15S	The second tier public warehouses are ISO certified	Yes ⊠ No □		
7.02.16S	Comments and References	Reference question 7.02.09S: The Channel suse and generates the percentages of medical Central Medical Stores is GDP certified by U	ines availab	
	te Sector Distribution			
			Year	Source
		Yes ⊠ No □	Year 2001	Source Pharmacy Act
Core Quest	cions (click here for help)  Legal provisions exist for licensing	Yes ⊠ No □		Pharmacy
7.03.01	Legal provisions exist for licensing wholesalers in the private sector  Legal provisions exist for licensing		2001	Pharmacy Act Phamacy
7.03.01 7.03.02	Legal provisions exist for licensing wholesalers in the private sector  Legal provisions exist for licensing distributors in the private sector  List of GDP certified wholesalers in	Yes ⊠ No □	2001	Pharmacy Act Phamacy Act Pharmact

#### Section 8 Selection and rational use 8.00 Respondent Information Section 7 8.00.01 Name of person responsible for Dennis Thomas, Directorate of Drugs and Medical Supplies, Minsitry filling out this section of the of Health and Sanitation instrument 8.00.02 Phone number 00 232 76 606367 8.00.03 Email address denntamba@yahoo.com 8.00.04 Other respondents for filling out this Mr Wilshire Johnson, Registrar, Pharmacy Board of Sierra Leone section 8.01 National Structures Core Questions (click here for help) Source Year 8.01.01 Yes ⊠ No □ 2004 National <u>essential medicines list</u> WHO level (EML) exists. If yes, please write year of last update of EML in the "year" field 8.01.01.01 If yes, number of medicines on the 438 EML (no. of INN) 8.01.01.02 If yes, there is a written process for Yes ⊠ No □ selecting medicines on the EML 8.01.01.03 If yes, the EML is publicly available Yes $\boxtimes$ No $\square$ 8.01.01.04 Yes ⊠ No □ If yes, is there any mechanism in place to align the EML with the Standard Treatment Guidelines (STG) 8.01.02 National Standard Treatment Yes ⊠ No □ 2006 WHO level Guidelines (STGs) for most common illnesses are produced/endorsed by the MoH. If yes, please insert year of last update of STGs in the "year" field 8.01.03 Yes ☐ No 🖂 STGs specific to Primary care exist. Please use the "year" field to

	write the year of last undets of			
	write the year of last update of primary care guidelines			
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 ⊠		
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
8.01.06	% of public health facilities with copy of EML (mean)- Survey data	0		
8.01.07	% of public health facilities with copy of STGs (mean)- Survey data	0		
8.01.08	A public or independently funded national medicines information centre provides information on medicines to prescribers, dispensers and consumers	Yes ⊠ No □	2007	WHO level I
8.01.09	Public education campaigns on rational medicine use topics have been conducted in the previous two years	Yes ⊠ No □		
8.01.10	A survey on rational medicine use has been conducted in the previous two years	Yes ⊠ No □		
8.01.11	A national programme or committee (involving government, civil society, and professional bodies) exists to monitor and promote rational use of medicines	Yes □ No ⊠	2007	WHO level I
8.01.12	A written National strategy exists to contain <u>antimicrobial resistance</u> . If yes, please write year of last update of the strategy in the "year" field	Yes □ No ⊠	2007	WHO level I

8.01.13	Comments and References	A national STG exist where primary and secondary care are all taken care-off.		
Suppleme	ntary questions (click here for he	elp)		
			Year	Source
8.01.14S	The Essential Medicines List (EML) includes formulations specific for children	Yes ⊠ No □		
8.01.15S	There are explicitly documented criteria for the selection of medicines in the EML	Yes ⊠ No □		
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
8.01.16.01S	If yes, conflict of interest declarations are required from members of national EML committee	Yes □ No ⊠		
8.01.17S	National medicines formulary exists	Yes □ No ⊠	2007	WHO level
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
8.01.19S	A national reference laboratory/or any other institution has responsibility for coordinating epidemiological surveillance of antimicrobial resistance	Yes ⊠ No □	2007	WHO level
8.01.20S	Comments and References			
8.02 Presci	ribing			
Core Quest	ions (click here for help)			
			Year	Source

8.02.01	Legal provisions exist to govern the licensing and prescribing practices of prescriber	Yes ⊠ No □	2007	WHO level
8.02.02	Legal provisions exist to restrict dispensing by prescribers	Yes ⊠ No □		
8.02.03	Do prescribers in the private sector dispense medicines?	Yes ⊠ No □	2007	WHO Level
8.02.04	Regulations require hospitals to organize/develop <u>Drug and</u> <u>Therapeutics Committees (DTCs)</u>	Yes □ No ⊠	2007	WHO level
8.02.05	Do more than half of <u>referral</u> hospitals have a DTC?	Yes ☐ No ☑ Unknown ☐	2007	WHO Level
8.02.06	Do more than half of general hospitals have a DTC?	Yes ☐ No ☑ Unknown ☐	2007	WHO Level
8.02.07	Do more than half of regions/provinces have a DTC?	Yes ☐ No ☒ Unknown ☐	2007	WHO Level
8.02.08	The core medical training curriculum includes components on:			
8.02.08.01	Concept of EML	Yes ⊠ No □		
8.02.08.02	Use of <u>STGs</u>	Yes ⊠ No □		
8.02.08.03	<u>Pharmacovigilance</u>	Yes ⊠ No □		
8.02.08.04	Problem based pharmacotherapy	Yes ⊠ No □		
8.02.09	Mandatory continuing education that includes pharmaceutical issues is required for doctors (see <a href="physician">physician</a> )	Yes ⊠ No □	2007	WHO
8.02.10	Mandatory continuing education that includes pharmaceutical issues is required for nurses	Yes ⊠ No □		
8.02.11	Mandatory continuing education that includes pharmaceutical issues is required for paramedical staff	Yes ⊠ No □	2007	WHO level

8.02.12	Prescribing by <u>INN</u> name is obligatory in:		2007	WHO level
8.02.12.01	Public sector	Yes ⊠ No □		
8.02.12.02	Private sector	Yes □ No ⊠		
8.02.13	Average number of medicines prescribed per patient contact in public health facilities (mean)	3		
8.02.14	% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)	70		
8.02.15	% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)	70		
8.02.16	% of patients in outpatient public health care facilities receiving antibiotics (mean)	50		
8.02.17	% of patients in outpatient public health care facilities receiving injections (mean)	50		
8.02.18	% of prescribed drugs dispensed to patients (mean)	70		
8.02.19	% of medicines adequately labeled in public health facilities (mean)	80		
8.02.20	Comments and References			
Suppleme	ntary questions ( <u>click here for he</u>	elp)		
			Year	Source
8.02.21S	A professional association code of conduct exists governing professional behaviour of doctors	Yes ⊠ No □		
8.02.22\$	A professional association code of conduct exists governing professional behaviour of nurses	Yes ⊠ No □		

8.02.23S	Diarrhoea in children treated with Oral Rehydration Solution (ORS) (%)	0		
8.02.24S	Comments and References			
0.02 D:	a da a			
8.03 Dispe				
Core Quest	ions (click here for help)			
			Year	Source
8.03.01	Legal provisions exist to govern dispensing practices of pharmaceutical personnel	Yes ⊠ No □		
8.03.02	The basic pharmacist training curriculum includes components on:			
8.03.02.01	Concept of EML	Yes ⊠ No □		
8.03.02.02	Use of STGs	Yes ⊠ No □		
8.03.02.03	Drug Information	Yes ⊠ No □		
8.03.02.04	Clinical pharmacology	Yes ⊠ No □		
8.03.02.05	Medicines supply management	Yes ⊠ No □		
8.03.03	Mandatory continuing education that includes rational use of medicines is required for pharmacists	Yes ⊠ No □	2007	WHO level
8.03.04	Generic substitution at the point of dispensing in public sector facilities is allowed	Yes ⊠ No □	2007	WHO level
8.03.05	Generic substitution at the point of dispensing in private sector facilities is allowed	Yes ⊠ No □	2007	WHO level
8.03.06	In practice, (even though this may be contrary to regulations) are antibiotics sometimes sold over-	Yes ⊠ No □ Unknown □	2007	WHO Level

	prescription?			
8.03.07	In practice, (even though this may be contrary to regulations) are injections sometimes sold over-the- counter without any prescription?	Yes ⊠ No ☐ Unknown ☐	2007	WHO Level
8.03.08	Comments and References			
Suppleme	ntary questions ( <u>click here for he</u>	<mark>elp</mark> )		
			Year	Source
8.03.09\$	A professional association code of conduct exists governing professional behaviour of pharmacists	Yes ⊠ No □		
8.03.10S	In practice, (even though this may be contrary to regulations) do the following groups of staff sometimes prescribe prescription-only medicines at the primary care level in the public sector?		2007	WHO level
8.03.10.01S	Nurses	Yes ⊠ No □ Unknown □		
8.03.10.02S	Pharmacists	Yes ⊠ No ☐ Unknown ☐		
8.03.10.03S	Paramedics <b>?</b>	Yes ⊠ No ☐ Unknown ☐		
8.03.10.04S	Personnel with less than one month training	Yes ☐ No ⊠ Unknown ☐		
8.03.11S	Comments and References			

## Section 9 Household data/access

### 9.00 Respondent Information section 8

9.00.01	Name of person responsible for filling out this section of the instrument	Mr I. G. Kargbo, Statistics Sierra Leone. Tower Hill. Freetown. Sierra Leone.
9.00.02	Phone number	00232 76 610851
9.00.03	Email address	igibrilj@yahoo.com
9.00.04	Other respondents for filling out this section	

## 9.01 Data from Household Surveys

# Core Questions (click here for help)

			Year	Source
9.01.01	What household surveys have been undertaken in the past 5 years to assess access to medicines?	None		
9.01.02	Adults with acute condition in two- week recall period who took all medicines prescribed by an authorized prescriber (%)	Data not available		
9.01.03	Adults with acute conditions not taking all medicines because they cannot afford them (%)	Data not available		
9.01.04	Adults (from poor households) with an acute health condition in two- week recall period who took all medicines prescribed by an authorized prescriber (%)	Data not available		
9.01.05	Adults (from poor households) with an acute condition in two-week recall period who did not take all medicines because they cannot afford them (%)	Data not available		

9.01.06	Adults with chronic conditions taking all medicines prescribed by an authorized prescriber (%)	Data not available			
9.01.07	Adults (from poor households) with chronic conditions not taking all medicines because they cannot afford them (%)	Data not available			
9.01.08	Adults (from poor households) with chronic conditions who usually take all medicines prescribed by an authorized prescriber (%)	Data not available			
9.01.09	Children (from poor households) with an acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)	Data not available			
9.01.10	Percentage of people that obtained the medicines prescribed in the 15 days before the interview (%)	Data not available			
9.01.11	People that obtained prescribed medicines for free in the 15 days before the interview (%)	Data not available			
9.01.12	Comments and References	No survey conducted on access to medicines.			
Suppleme	ntary questions ( <u>click here for he</u>	elp)			
			Year	Source	
9.01.13S	Adults with acute conditions not taking all medicines because the medicines were not available (%)	Data not available			
9.01.14S	Adults with chronic conditions not taking all medicines because they cannot afford them (%)	Data not available			
9.01.15S	Adults with chronic conditions not taking all medicines because the medicines were not available (%)	Data not availabe			
9.01.16S	Children with acute conditions taking all medicines prescribed by				

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

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