World Health Organization

Investing in our future
The Global Fund
To Fight AIDS, Tuberculosis and Malaria

Pharmaceutical Sector Country Profile Questionnaire

INSERT COUNTRY NAME

The Pharmaceutical Sector Country Profile Survey

1. Background and Rationale:

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

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

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

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

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

2. What can Pharmaceutical Sector Country Profiles offer:

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

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

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

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

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

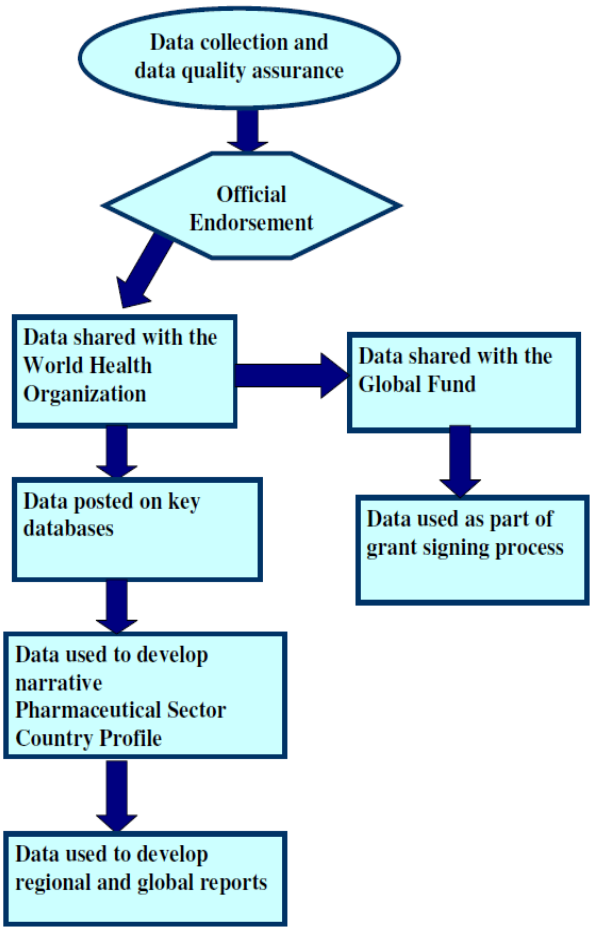
V) The data collected could be transformed into a narrative report with robust data analysis and bibliographic references, that will summarize the medicines situation in the country.

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

3. The process of data collection and analysis:

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

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



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

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

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

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

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

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

Please read these instructions carefully before starting data collection

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

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

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

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

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

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

5. Possible answers:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

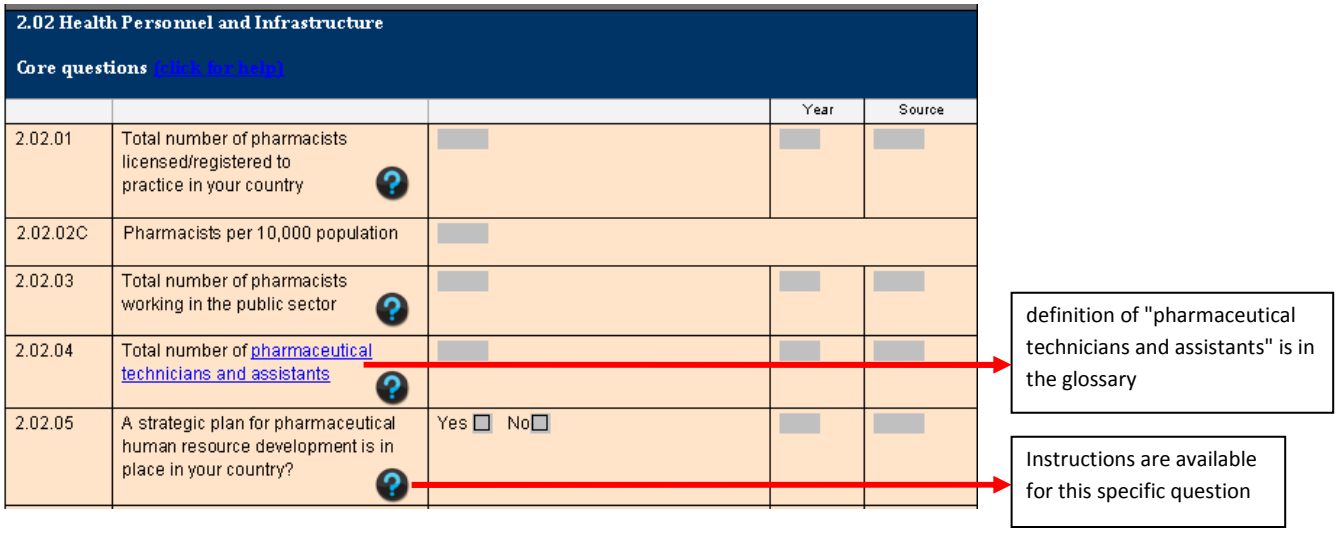
These documents will be published on the WHO web site's medicines library (http://apps.who.int/medicinedocs/en/) and will therefore have to be endorsed by the Ministry of Health prior to being made publicly available. You can send us these documents by e-mail as attachments or you can upload them into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

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

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

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

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

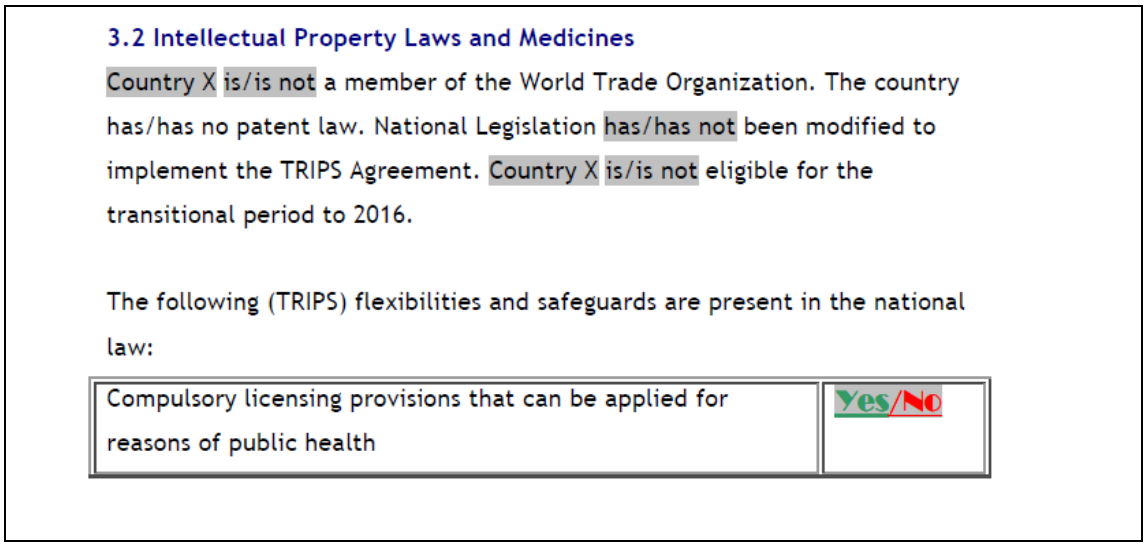


13. Respondents and acknowledgements: at the beginning of every section there are fields available to fill in details about the respondent for that particular section. It is also possible to enter the details of multiple respondents. At the end of the instrument please add a list of contributors who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

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

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

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



3.2 Intellectual Property Laws and Medicines

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

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

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

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

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

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

Section 0 General Info

0.01 Contact Info

0.01.01	Country (precoded)	
0.01.02	Name coordinator	
0.01.03	Address (Street, City)	
0.01.04	Phone number	
0.01.05	Email address	
0.01.06	Web address	
0.01.07	Institution	

Section 1 Health and Demographic data

1.00 Respondent Information Section 1

1.00.01	Name of person responsible for filling out Survey section 1	
1.00.02	Phone number	
1.00.03	Email address	
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)			
1.01.02	Population growth rate (Annual %)			
1.01.03	Total Gross Domestic Product (GDP) (millions US$)			
1.01.04	GDP growth (Annual %)			
1.01.05C	GDP per capita (US$ current exchange rate)			
1.01.06	Comments and References			

Supplementary questions (click here for help)

			Year	Source
1.01.07S	Population < 15 years (% of total population)			
1.01.08S	Population > 60 years (% of total population)			
1.01.09S	Urban population (% of total population)			
1.01.10S	Fertility rate, total (Births per woman)			

1.01.11S	Population living with less than $1.25/day (international PPP) (%)			
1.01.12S	Population living below nationally defined poverty line (%)			
1.01.13S	Income share held by lowest 20% of the population (% of national income)			
1.01.14S	Adult literacy rate, 15+ years (% of relevant population)			
1.01.15S	Comments and References			

1.02 Mortality and Causes of Death

Core questions (click here for help)

			Year	Source
1.02.01	Life expectancy at birth for men (Years)			
1.02.02	Life expectancy at birth for women (Years)			
1.02.03	Infant mortality rate, between birth and age 1 (/1,000 live births)			
1.02.04	Under 5 mortality rate (/1,000 live births)			
1.02.05	Maternal mortality ratio (/100,000 live births)			
1.02.06	Please provide a list of top 10 diseases causing mortality			
1.02.06.01	Disease 1			
1.02.06.02	Disease 2			
1.02.06.03	Disease 3			
1.02.06.04	Disease 4			

1.02.06.05	Disease 5			
1.02.06.06	Disease 6			
1.02.06.07	Disease 7			
1.02.06.08	Disease 8			
1.02.06.09	Disease 9			
1.02.06.10	Disease 10			
1.02.07	Please provide a list of top 10 diseases causing morbidity 			
1.02.07.01	Disease 1			
1.02.07.02	Disease 2			
1.02.07.03	Disease 3			
1.02.07.04	Disease 4			
1.02.07.05	Disease 5			
1.02.07.06	Disease 6			
1.02.07.07	Disease 7			
1.02.07.08	Disease 8			
1.02.07.09	Disease 9			
1.02.07.10	Disease 10			
1.02.08	Comments and References			

Supplementary questions (click here for help)

			Year	Source
1.02.09S	Adult mortality rate for both sexes between 15 and 60 years (/1,000 population)			
1.02.10S	Neonatal mortality rate (/1,000 live			

	births)			
1.02.11S	Age-standardized mortality rate by non-communicable diseases (/100,000 population)			
1.02.12S	Age-standardized mortality rate by cardiovascular diseases (/100,000 population)			
1.02.13S	Age-standardized mortality rate by cancer (/100,000 population)			
1.02.14S	Mortality rate for HIV/AIDS (/100,000 population)			
1.02.15S	Mortality rate for tuberculosis (/100,000 population)			
1.02.16S	Mortality rate for Malaria (/100,000 population)			
1.02.17S	Comments and References			

Section 2 Health Services

2.00 Respondent Information Section 2

2.00.01	Name of person responsible for filling out this section of the instrument	
2.00.02	Phone number	
2.00.03	Email address	
2.00.04	Other respondents for filling out this section	

2.01 Health Expenditures

Core questions (click here for help)

			Year	Source
2.01.01.01	Total annual expenditure on health (millions NCU)			
2.01.01.02	Total annual expenditure on health (millions US$ average exchange rate)			
2.01.02C	Total health expenditure as % of Gross Domestic Product			
2.01.03.01C	Total annual expenditure on health per capita (NCU)			
2.01.03.02C	Total annual expenditure on health per capita (US$ average exchange rate)			
2.01.04.01	General government annual expenditure on health (millions NCU)			
2.01.04.02	General government annual expenditure on health (millions US$ average exchange rate)			
2.01.05	Government annual expenditure on 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)			
2.01.07.01C	Annual per capita government expenditure on health (NCU)			
2.01.07.02C	Annual per capita government expenditure on health (US$ average exchange rate)			
2.01.08C	Private health expenditure as % of total health expenditure (% of total expenditure on health)			
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) 			
2.01.10	Population covered by private health insurance (% of total population) 			
2.01.11.01	Total pharmaceutical expenditure (millions NCU)			
2.01.11.02	Total pharmaceutical expenditure (millions US$ current exchange rate)			
2.01.12.01C	Total pharmaceutical expenditure per capita (NCU)			
2.01.12.02C	Total pharmaceutical expenditure per capita (US$ current exchange rate)			
2.01.13C	Pharmaceutical expenditure as a % of GDP (% of GDP)			
2.01.14C	Pharmaceutical expenditure as a % of Health Expenditure (% of total health expenditure)			
2.01.15.01	Total public expenditure on			

	pharmaceuticals (millions NCU)			
2.01.15.02	Total public expenditure on 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 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			

Supplementary questions (click for help)

			Year	Source
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 (%)			
2.01.23S	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)			
2.01.25S	Premiums for private prepaid health plans as % of total private health expenditure (% of private expenditure on health)			
2.01.26S	Comments and References			

2.02 Health Personnel and Infrastructure

Core questions (click for help)

			Year	Source
2.02.01	Total number of pharmacists licensed/registered to practice in your country			
2.02.02C	Pharmacists per 10,000 population			
2.02.03	Total number of pharmacists working in the public sector			
2.02.04	Total number of pharmaceutical technicians and assistants			
2.02.05	A strategic plan for pharmaceutical human resource development is in place in your country?	Yes ☐ No ☐		
2.02.06	Total number of physicians			
2.02.07C	Physicians per 10,000 pop			
2.02.08	Total number of nursing and midwifery personnel			
2.02.09C	Nurses and midwives per 10,000 pop			
2.02.10	Total number of hospitals			
2.02.11	Number of hospital beds per 10,000			

	pop			
2.02.12	Total number of primary health care units and centers			
2.02.13	Total number of licensed pharmacies			
2.02.14	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
2.02.15S	Starting annual salary for a newly registered pharmacist in the public sector (NCU)			
2.02.16S	Total number of pharmacists who graduated (first degree) in the past 2 years in your country			
2.02.17S	Are there accreditation requirements for pharmacy schools?	Yes ☐ No☐		
2.02.18S	Is the Pharmacy Curriculum regularly reviewed?	Yes ☐ No ☐		
2.02.19S	Comments and References			

Section 3 Policy issues

3.00 Respondent Information Section 4

3.00.01	Name of person responsible for filling out this section of the instrument			
3.00.02	Phone number			
3.00.03	Email address			
3.00.04	Other respondents for filling out this section			

3.01 Policy Framework

Core questions (click here for help)

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

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

3.01.11	There are official written guidelines on medicines donations.	Yes ☐ No ☐		
3.01.12	Is pharmaceutical policy implementation being regularly monitored/assessed?	Yes ☐ No ☐		
3.01.12.01	Who is responsible for pharmaceutical policy monitoring?			
3.01.13	Is there a national good governance policy?	Yes ☐ No ☐		
3.01.13.01	Multisectoral	☐Yes		
3.01.13.02	For the pharmaceutical sector	☐Yes		
3.01.13.03	Which agencies are responsible?			
3.01.14	A policy is in place to manage and sanction conflict of interest issues in pharmaceutical affairs.	Yes ☐ No ☐		
3.01.15	There is a formal code of conduct for public officials.	Yes ☐ No ☐		
3.01.16	Is there a whistle-blowing mechanism allowing individuals to raise a concern about wrongdoing occurring in the pharmaceutical sector of your country (ombudsperson)?	Yes ☐ No ☐		
3.01.16.01	Please describe:			
3.01.17	Comments and References			

Section 4 Medicines Trade and Production

4.00 Respondent Information Section 4

4.00.01	Name of person responsible for filling out this section of the instrument	
4.00.02	Phone number	
4.00.03	Email address	
4.00.04	Other respondents for filling out this section	

4.01 Intellectual Property Laws and Medicines

Core questions (click here for help)

			Year	Source
4.01.01	Country is a member of the World Trade Organization	Yes ☐ No☐		
4.01.02	Legal provisions provide for granting of Patents on:			
4.01.02.01	Pharmaceuticals	Yes ☐ No☐		
4.01.02.02	Laboratory supplies	Yes ☐ No ☐		
4.01.02.03	Medical supplies	Yes ☐ No ☐		
4.01.02.04	Medical equipment	Yes ☐ No ☐		
4.01.03.01	Please provide name and address of the institution responsible for managing and enforcing intellectual property rights			
4.01.03.02	Please provide URL			
4.01.04	National Legislation has been modified to implement the TRIPS Agreement	Yes ☐ No ☐		
4.01.05	Current laws contain (TRIPS)	Yes ☐ No☐		

	flexibilities and safeguards			
4.01.06	Country is eligible for the transitional period to 2016	Yes ☐ No☐		
4.01.07	Which of the following (TRIPS) flexibilities and safeguards are present in the national law?			
4.01.07.01	Compulsory licensing provisions that can be applied for reasons of public health	Yes ☐ No ☐		
4.01.07.02	Bolar exception	Yes ☐ No ☐		
4.01.08	Are parallel importing provisions present in the national law?	Yes ☐ No ☐		
4.01.09	The country is engaged in initiatives to strengthen capacity to manage and apply intellectual property rights to contribute to innovation and promote public health	Yes ☐ No ☐		
4.01.10	Are there legal provisions for data exclusivity for pharmaceuticals	Yes ☐ No ☐		
4.01.11	Legal provisions exist for patent extension	Yes ☐ No ☐		
4.01.12	Legal provisions exist for linkage between patent status and Marketing Authorization	Yes ☐ No ☐		
4.01.13	Comments and References			

4.02 Manufacturing

Core questions (click here for help)

			Year	Source
4.02.01	Number of licensed pharmaceutical manufacturers in the country			
4.02.02	Country has manufacturing capacity			

4.02.02.01	R&D to discover new active substances	Yes ☐ No ☐ Unknown ☐		
4.02.02.02	Production of pharmaceutical starting materials (APIs)	Yes ☐ No ☐ Unknown ☐		
4.02.02.03	Production of formulations from pharmaceutical starting material	Yes ☐ No ☐ Unknown ☐		
4.02.02.04	Repackaging of finished dosage forms	Yes ☐ No ☐ Unknown ☐		
4.02.03	Percentage of market share by value produced by domestic manufacturers (%)			
4.02.04	Comments and References			

Supplementary questions (click here for help)

			Year	Source
4.02.05S	Percentage of market share by volume produced by domestic manufacturers (%)			
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			

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	
5.00.02	Phone number	
5.00.03	Email address	
5.00.04	Other respondents for filling out this section	

5.01 Regulatory Framework

Core questions (click here for help)

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

5.01.05.01	Marketing authorization / registration	Yes ☐ No ☐		
5.01.05.02	Inspection	Yes ☐ No ☐		
5.01.05.03	Import control	Yes ☐ No ☐		
5.01.05.04	Licensing	Yes ☐ No ☐		
5.01.05.05	Market control	Yes ☐ No ☐		
5.01.05.06	Quality control	Yes ☐ No ☐		
5.01.05.07	Medicines advertising and promotion	Yes ☐ No ☐		
5.01.05.08	Clinical trials control	Yes ☐ No ☐		
5.01.05.09	Pharmacovigilance	Yes ☐ No ☐		
5.01.05.10	Other: (please explain)			
5.01.06	Number of the MRA permanent staff			
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)			
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 ☐		
5.01.09.01	- If yes, please specify			
5.01.10	An assessment of the medicines regulatory system has been conducted in the last five years.	Yes ☐ No ☐		
5.01.11	Medicines Regulatory Authority gets funds from regular budget of the	Yes ☐ No ☐		

	government.			
5.01.12	Medicines Regulatory Authority is funded from fees for services provided.	Yes ☐ No ☐		
5.01.13	Medicines Regulatory Authority receives funds/support from other sources	Yes ☐ No ☐		
5.01.13.01	- If yes, please specify			
5.01.14	Revenues derived from regulatory activities are kept with the Regulatory Authority	Yes ☐ No ☐		
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			

5.02 Marketing Authorization (Registration)

Core questions (click here for help)

			Year	Source
5.02.01	Legal provisions require a Marketing Authorization (registration) for all pharmaceutical products on the market	Yes ☐ No ☐		
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:			

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 prequalification programme managed by WHO is used for product registration	Yes ☐ No ☐		
5.02.06	Number of pharmaceutical products registered in your country			
5.02.07	Legal provisions require the MRA to make the list of registered pharmaceuticals with defined periodicity publicly available	Yes ☐ No ☐		
5.02.07.01	If yes, how frequently updated			
5.02.07.02	If yes, please provide updated list or URL *			
5.02.08	Medicines registration always includes the INN (International Non-proprietary Names)	Yes ☐ No ☐		
5.02.09	Legal provisions require the payment of a fee for Medicines Marketing Authorization (registration) applications	Yes ☐ No ☐		
5.02.10	Comments and References			

Supplementary questions (click here for help)

			Year	Source
5.02.11S	Legal provisions require Marketing Authorization holders to provide information about variations to the existing Marketing Authorization	Yes ☐ No ☐		
5.02.12S	Legal provisions require publication of a Summary of Product Characteristics (SPCs) of the medicines registered	Yes ☐ No ☐		

5.02.13S	Legal provisions require the establishment of an expert committee involved in the marketing authorization process	Yes ☐ No ☐		
5.02.14S	Certificate for Pharmaceutical Products in accordance with the WHO Certification scheme is required as part of the Marketing Authorization application	Yes ☐ No ☐		
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$)			
5.02.18S	Registration fee - the Amount per application for a generic pharmaceutical product (US$)			
5.02.19S	Time limit for the assessment of a Marketing Authorization application (months)			
5.02.20S	Comments & References			

5.03 Regulatory Inspection

Core Questions(click here for help)

			Year	Source
5.03.01	Legal provisions exist allowing for appointment of government pharmaceutical inspectors	Yes ☐ No ☐		
5.03.02	Legal provisions exist permitting	Yes ☐ No ☐		

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

5.04 Import Control

Core Questions (click here for help)

			Year	Source
5.04.01	Legal provisions exist requiring authorization to import medicines	Yes ☐ No ☐		

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 Licensing

			Year	Source
5.05.01	Legal provisions exist requiring manufacturers to be licensed	Yes ☐ No ☐		
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 ☐		
5.05.05	Legal provisions exist requiring wholesalers and distributors to be licensed	Yes ☐ No ☐		
5.05.06	Legal provisions exist requiring wholesalers and distributors to comply with Good Distributing Practices **When filling in this part, please also fill in the relevant questions in the procurement and distribution**	Yes ☐ No ☐		

	section (Section 7)			
5.05.07	National Good Distribution Practice requirements are published by the government	Yes ☐ No ☐		
5.05.08	Legal provisions exist requiring pharmacists to be registered	Yes ☐ No ☐		
5.05.09	Legal provisions exists requiring private pharmacies to be licensed	Yes ☐ No ☐		
5.05.10	Legal provision exist requiring public pharmacies to be licensed	Yes ☐ No ☐		
5.05.11	National Good Pharmacy Practice Guidelines are published by the government	Yes ☐ No ☐		
5.05.12	Legal provisions require the publication of a list of all licensed pharmaceutical facilities	Yes ☐ No ☐		
5.05.13	Comments and References			

5.06 Market Control and Quality Control

Core Questions (click here for help)

			Year	Source
5.06.01	Legal Provisions for regulating the pharmaceutical market exist	Yes ☐ No ☐		
5.06.02	Does a laboratory exist in the country for Quality Control testing?	Yes ☐ No ☐		
5.06.02.01	If yes, is the laboratory part of the MRA?	Yes ☐ No ☐		
5.06.02.02	Does the regulatory authority contract services elsewhere?	Yes ☐ No ☐		
5.06.02.03	If yes, please describe			
5.06.03	Is there any national laboratory accepted for collaboration with WHO			

	prequalification Programme? Please describe.			
5.06.04	Medicines are tested:			
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 ☐		
5.06.06	How many Quality Control samples were taken for testing in the last two years?			
5.06.07	Total number of samples tested in the last two years that failed to meet quality standards			
5.06.08	Results of quality testing in past two years are publicly available	Yes ☐ No ☐		
5.06.09	Comments and References			

5.07 Medicines Advertising and Promotion

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

5.07.06.03	If yes, the code contains a formal process for complaints and sanctions	Yes ☐ No ☐		
5.07.06.04	If yes, list of complaints and sanctions for the last two years is publicly available	Yes ☐ No ☐		
5.07.07	Comments and References			

5.08 Clinical trials

Core Questions (click here for help)

			Year	Source
5.08.01	Legal provisions exist requiring authorization for conducting Clinical 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 questions (click here for help)

			Year	Source
5.08.05S	Legal provisions exist for GMP compliance of investigational products	Yes ☐ No ☐		
5.08.06S	Legal provisions require sponsor, investigator to comply with Good Clinical Practices (GCP)	Yes ☐ No ☐		
5.08.07S	National GCP regulations are published by the Government.	Yes ☐ No ☐		

5.08.08S	Legal provisions permit inspection of facilities where clinical trials are performed	Yes ☐ No ☐		
5.08.09S	Comments and References			

5.09 Controlled Medicines

Core Questions (click here for help)

			Date	Source
5.09.01	The country has adopted the following conventions:			
5.09.01.01	Single Convention on Narcotic Drugs, 1961	Yes ☐ No ☐		
5.09.01.02	The 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	Yes ☐ No ☐		
5.09.01.03	Convention on Psychotropic Substances 1971	Yes ☐ No ☐		
5.09.01.04	United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	Yes ☐ No ☐		
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)			
5.09.04	Comments and References			

Supplementary questions (click here for help)

			Year	Source
5.09.05S	The legal provisions and regulations for the control of narcotic and psychotropic substances, and precursors have been reviewed by a WHO International Expert or Partner Organization to assess the balance	Yes ☐ No ☐ Unknown ☐		

	between the prevention of abuse and access for medical need			
5.09.05.01S	If yes, year of review			
5.09.06S	Annual consumption of Fentanyl (mg/capita)			
5.09.07S	Annual consumption of Pethidine (mg/capita)			
5.09.08S	Annual consumption of Oxycodone (mg/capita)			
5.09.09S	Annual consumption of Hydrocodone (mg/capita)			
5.09.10S	Annual consumption of Phenobarbital (mg/capita)			
5.09.11S	Annual consumption of Methadone (mg/capita)			
5.09.12S	Comments and References			

5.10 Pharmacovigilance

Core Questions (click here for help)

			Year	Source
5.10.01	There are legal provision in the Medicines Act that provides for pharmacovigilance activities as part of the MRA mandate	Yes ☐ No ☐		
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	Yes ☐ No ☐		

	country			
5.10.04.01	If a national pharmacovigilance centre exists in your country, how many staff does it employ full-time			
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?			
5.10.08	How many reports have been submitted in the last two years?			
5.10.09	Are ADR reports sent to the WHO database in Uppsala?	Yes ☐ No ☐		
5.10.09.01	If yes, number of reports sent in the last two years			
5.10.10	Is there a national ADR or pharmacovigilance advisory committee able to provide technical assistance on causality assessment, 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	Yes ☐ No ☐		

	and crises communication?			
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			
5.10.14	Comments and References			
Supplementary questions (click here for help)				
			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 ☐		
5.10.18S	How many MEs are there in the ADRs database?			
5.10.19S	There is a risk management plan presented as part of product dossier submitted for Marketing Authorization?	Yes ☐ No ☐		
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☐		
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?			
5.10.23S	Comments and References			

Section 6 Medicines Financing

6.00 Respondent Information Section 5

6.00.01	Name of person responsible for filling out this section of the instrument	
6.00.02	Phone number	
6.00.03	Email address	
6.00.04	Other respondents for this sections	

6.01 Medicines Coverage and Exemptions

Core Questions (click here for help)

			Year	Source
6.01.01	Do the followings receive medicines free of charge:			
6.01.01.01	Patients who cannot afford them	Yes ☐ No☐		
6.01.01.02	Children under 5	Yes ☐ No☐		
6.01.01.03	Pregnant women	Yes ☐ No☐		
6.01.01.04	Elderly persons	Yes ☐ No☐		
6.01.01.05	Please describe/explain your yes answers for questions above			
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	Any non-communicable diseases	Yes ☐ No ☐		
6.01.02.03	Malaria medicines	Yes ☐ No ☐		
6.01.02.04	Tuberculosis medicines	Yes ☐ No ☐		
6.01.02.05	Sexually transmitted diseases	Yes ☐ No ☐		

	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	
6.01.03	Does a national health insurance, social insurance or other sickness fund provide at least partial medicines coverage?	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 Patients Fees and Copayments

Core Questions (click here for help)

			Year	Source
6.02.01	In your health system, at the point of delivery, are there any co-payment/fee requirements for	Yes ☐ No ☐		

	consultations			
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 ☐		
6.02.03.01	Please describe the patient fees and copayments system			
6.02.04	Comments and References			

6.03 Pricing Regulation for the Private Sector

Core Questions (click here for help)

			Year	Source
6.03.01	Are there legal or regulatory provisions affecting pricing of medicines	Yes ☐ No ☐		
6.03.01.01	If yes, are the provisions aimed at Manufacturers	Yes ☐ No ☐		
6.03.01.02	If yes, are the provisions aimed at Wholesalers	Yes ☐ No ☐		
6.03.01.03	If yes, are the provisions aimed at Retailers	Yes ☐ No ☐		
6.03.01.04	Please explain the positive answers above: (explain scope of provisions i.e generics vs. originator or subsets of medicines, EML etc.)			
6.03.02	Government runs an active national medicines price monitoring system for retail prices	Yes ☐ No ☐		

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

6.04 Prices, Availability and Affordability

Core Questions (click here for help)

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

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

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

6.05 Price Components and Affordability

Core Questions (click here for help)

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

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

6.06 Duties and Taxes on Pharmaceuticals (Market)		
Core Questions (click here for help)		
	Year	Source

6.06.01	There are duties on imported active pharmaceutical ingredients (APIs)	Yes ☐ No ☐		
6.06.02	There are duties on imported finished products	Yes ☐ No ☐		
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			
6.06.06	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
6.06.07S	Duty on imported active pharmaceutical ingredients, APIs (%)			
6.06.08S	Duty on imported finished products (%)			
6.06.09S	VAT on pharmaceutical products (%)			
6.06.10S	Comments and References			

Section 7 Pharmaceutical procurement and distribution

7.00 Respondent Information Section 6

7.00.01	Name of person responsible for filling out this section of the instrument	
7.00.02	Phone number	
7.00.03	Email address	
7.00.04	Other respondents for filling out this section	

7.01 Public Sector Procurement

Core Questions (click here for help)

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

7.01.02.04	A government procurement agency which procures all public goods	Yes ☐ No ☐		
7.01.03	Public sector requests for tender documents are publicly available	Yes ☐ No ☐		
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			
7.01.06	Comments and References			

Supplementary questions (click here for help)

			Year	Source
7.01.07S	Is there a written public sector procurement policy?. If yes, please write the year of approval in the "year" field	Yes ☐ No ☐		
7.01.08S	Are there legal provisions giving priority in public procurement to goods produced by local manufacturers?	Yes ☐ No ☐		
7.01.09S	The key functions of the procurement unit and those of the tender committee are clearly separated	Yes ☐ No ☐		
7.01.10S	A process exists to ensure the quality of products procured	Yes ☐ No ☐		
7.01.10.01S	If yes, the quality assurance process includes pre-qualification of products and suppliers	Yes ☐ No ☐		
7.01.10.02S	If yes, explicit criteria and procedures exist for pre-qualification of suppliers	Yes ☐ No ☐		
7.01.10.03S	If yes, a list of pre-qualified suppliers and products is publicly	Yes ☐ No ☐		

	available			
7.01.11S	List of samples tested during the procurement process and results of quality testing are available	Yes ☐ No ☐		
7.01.12S	Which of the following tender methods are used in public sector procurement:			
7.01.12.01S	National competitive tenders	Yes ☐ No ☐		
7.01.12.02S	International competitive tenders	Yes ☐ No ☐		
7.01.12.03S	Direct purchasing	Yes ☐ No ☐		
7.01.13S	Comments and References			

7.02 Public Sector Distribution

Core Questions (click here for help)

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

Supplementary questions (click here for help)

			Year	Source
7.02.08S	Which of the following processes is in place at the Central Medical Store:			
7.02.08.01S	Forecasting of order quantities	Yes ☐ No ☐		
7.02.08.02S	Requisition/Stock orders	Yes ☐ No ☐		
7.02.08.03S	Preparation of picking/packing slips	Yes ☐ No ☐		
7.02.08.04S	Reports of stock on hand	Yes ☐ No ☐		
7.02.08.05S	Reports of outstanding order lines	Yes ☐ No ☐		
7.02.08.06S	Expiry dates management	Yes ☐ No ☐		
7.02.08.07S	Batch tracking	Yes ☐ No ☐		
7.02.08.08S	Reports of products out of stock	Yes ☐ No ☐		
7.02.09S	Percentage % availability of key medicines at the Central Medical Store			
7.02.10S	Average stock-out duration for a basket of medicines at the Central Medical Store, in days			
7.02.11S	Routine Procedure exists to track the expiry dates of medicines at the Central Medical Store	Yes ☐ No ☐		
7.02.12S	The Public Central Medical Store is GDP certified by a licensing authority	Yes ☐ No ☐		

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

7.03 Private Sector Distribution

Core Questions (click here for help)

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

Section 8 Selection and rational use

8.00 Respondent Information Section 7

8.00.01	Name of person responsible for filling out this section of the instrument	
8.00.02	Phone number	
8.00.03	Email address	
8.00.04	Other respondents for filling out this section	

8.01 National Structures

Core Questions (click here for help)

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

	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 ☐		
8.01.06	% of public health facilities with copy of EML (mean)- Survey data			
8.01.07	% of public health facilities with copy of STGs (mean)- Survey data			
8.01.08	A public or independently funded national medicines information centre provides information on medicines to prescribers, dispensers and consumers	Yes ☐ No ☐		
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 ☐		
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 ☐		

8.01.13	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
8.01.14S	The Essential Medicines List (EML) includes formulations specific for children	Yes ☐ No ☐		
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 ☐		
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 ☐		
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 ☐		
8.01.19S	A national reference laboratory/or any other institution has responsibility for coordinating epidemiological surveillance of antimicrobial resistance	Yes ☐ No ☐		
8.01.20S	Comments and References			
8.02 Prescribing **Core Questions (click here for help)**				
			Year	Source
8.02.01	Legal provisions exist to govern the licensing and prescribing practices	Yes ☐ No ☐		

	of prescriber			
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 ☐		
8.02.04	Regulations require hospitals to organize/develop Drug and Therapeutics Committees (DTCs)	Yes ☐ No ☐		
8.02.05	Do more than half of referral hospitals have a DTC?	Yes ☐ No ☐ Unknown ☐		
8.02.06	Do more than half of general hospitals have a DTC?	Yes ☐ No ☐ Unknown ☐		
8.02.07	Do more than half of regions/provinces have a DTC?	Yes ☐ No ☐ Unknown ☐		
8.02.08	The core medical training curriculum includes components on:			
8.02.08.01	Concept of EML	Yes ☐ No ☐		
8.02.08.02	Use of STGs	Yes ☐ No ☐		
8.02.08.03	Pharmacovigilance	Yes ☐ No ☐		
8.02.08.04	Problem based pharmacotherapy	Yes ☐ No ☐		
8.02.09	Mandatory continuing education that includes pharmaceutical issues is required for doctors (see physician)	Yes ☐ No ☐		
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 ☐		
8.02.12	Prescribing by INN name is			

	obligatory in:	☒Yes		
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)			
8.02.14	% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)			
8.02.15	% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)			
8.02.16	% of patients in outpatient public health care facilities receiving antibiotics (mean)			
8.02.17	% of patients in outpatient public health care facilities receiving injections (mean)			
8.02.18	% of prescribed drugs dispensed to patients (mean)			
8.02.19	% of medicines adequately labelled in public health facilities (mean)			
8.02.20	Comments and References			

Supplementary questions (click here for help)

			Year	Source
8.02.21S	A professional association code of conduct exists governing professional behaviour of doctors	Yes ☐ No ☐		
8.02.22S	A professional association code of conduct exists governing professional behaviour of nurses	Yes ☐ No ☐		

8.02.23S	Diarrhoea in children treated with Oral Rehydration Solution (ORS) (%)			
8.02.24S	Comments and References			

8.03 Dispensing

Core Questions (click here for help)

			Year	Source
8.03.01	Legal provisions exist to govern dispensing practices of pharmaceutical personnel	Yes ☐ No ☐		
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 ☐		
8.03.04	Generic substitution at the point of dispensing in public sector facilities is allowed	Yes ☐ No ☐		
8.03.05	Generic substitution at the point of dispensing in private sector facilities is allowed	Yes ☐ No ☐		
8.03.06	In practice, (even though this may be contrary to regulations) are antibiotics sometimes sold over-the-counter without any	Yes ☐ No ☐ Unknown ☐		

	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 ☐		
8.03.08	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
8.03.09S	A professional association code of conduct exists governing professional behaviour of pharmacists	Yes ☐ No ☐		
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?			
8.03.10.01S	Nurses 	Yes ☐ No ☐ Unknown ☐		
8.03.10.02S	Pharmacists 	Yes ☐ No ☐ Unknown ☐		
8.03.10.03S	Paramedics 	Yes ☐ No ☐ Unknown ☐		
8.03.10.04S	Personnel with less than one month training 	Yes ☐ No ☐ Unknown ☐		
8.03.11S	Comments and References			

Section 9 Household data/access

9.00 Respondent Information section 8

9.00.01	Name of person responsible for filling out this section of the instrument	
9.00.02	Phone number	
9.00.03	Email address	
9.00.04	Other respondents for filling out this section	

9.01 Data from Household Surveys

Core Questions (click here for help)

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

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

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

Key Documents to be attached

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

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

Manual for data collection