REPUBLIC OF GUINEA

COUNTRY PHARMACEUTICAL PROFILE

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Published by the Ministry of Health in collaboration with the World Health Organization
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2011

Users of this profile are invited to send their comments or requests to the following address :

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FOREWORD

Guinea Conakry's 2011 drug profile was produced by the Ministry of Health, in collaboration with the World Health Organization.

It contains information on the existing socio-economic conditions and those of health, as well as regulatory structures, procedures and outcomes relating to the pharmaceutical sector in Guinea. The data compiled here comes from international sources (e.g. World Health Statistics1,2), surveys conducted in recent years and information collected at the country level in 2011.
For each piece of information, the data sources are presented in the tables which are at the end of the document.

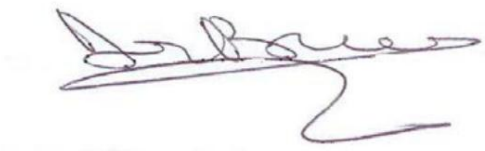
I hope this profile will be a useful tool for partners, researchers, political leaders and all those whom the pharmaceutical sector in Guinea interested in helping them in their activities.

Name: Bah Binta

Position at the Ministry of Health: Deputy National Director of Pharmacy at the National Directorate of Pharmacy and Laboratory (DNPL).

Date: June 16, 2011.

Signature:



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INTRODUCTION

The drug profile of the country presents data on socio-economic conditions existing economic and health, resources, structures regulations, processes and results relating to the pharmaceutical sector in Guinea. This document aims to compile all the existing information and relevant to the pharmaceutical sector and disseminate them to the general public in an accessible way. In 2010, 13 countries took part in the pilot project on profiles national (http://www.who.int/medicines/areas /coordination/coordination_assessment/en/index.html). In 2011, the World Health Organization supported all of its Member States to prepare similar comprehensive profiles.

The information is classified in 9 sections, namely: 1) Health data and demographics, 2) Health services, 3) Political aspects, 4) Trade and production of medicines, 5) Pharmaceutical regulations, 6) Financing of medicines, 7) Purchasing and distribution of pharmaceutical products, 8) Selection and rational use, 9) Household data/access. The indicators have been divided into two categories, the “main” indicators (the most important) and "additional" (useful if available). This descriptive profile derives of the two types of indicators. The tables in the appendices also give the data collected for each of the indicators on the original survey form. For each item of information, the year and the origin of the data are specified; we used them to establish the references for the profile and they are also indicated in the paintings. If key national documents are accessible online, the links have been been provided for easy reader access.

All technical units working in the Essential Medicines Department of the World Health Organization (WHO) were involved in the selection of indicators for the profiles, as well as experts from WHO offices in the

regions and countries, Harvard Medical School, the Oswaldo Cruz Foundation (called Fiocruz), the University of Utrecht, the Austrian Federal Institute for Health and representatives of the 13 pilot countries.

In all 193 Member States, data collection was done through an easy-to-use electronic questionnaire including very detailed instructions complete and a glossary. Countries were asked not to carry out surveys additional information but only to capture the results of previous surveys and provide the information available at the central level. To facilitate the work of national counterparts, the questionnaires were previously completed at the Headquarters of WHO with all publicly available data, before transmitting them to countries through WHO regional offices. A coordinator has been appointed in each Member State. For Guinea, the coordinators were Dr. FOFANA Mory and Dr. SANO Mariama Siré.

Once completed, the questionnaires were used to produce each country profile. To achieve this in a structured and efficient way, a model text has been developed. Experts from Member States participated in the development of the profile and, when the final document was ready, an official from the Ministry of Health certified the quality information and has officially authorized the publication of the profile on the website of WHO.

This profile will be regularly updated by the Ministry of Health and Hygiene of the Republic of Guinea. Observations, proposals or corrections may be sent to :

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SECTION 1 - HEALTH AND DEMOGRAPHIC DATA

The reader will find in this section an overview of the demographic situation and health in Guinea.

1.1 Demographic and socio-economic indicators

Guinea Conakry had a total population of 10,069,000 in 2009 with an annual growth rate of 0.2 %3 . The annual GDP growth rate is 1.9 %4 . the

GDP per capita was US$ 432.1 (at the current exchange rate).

1.2 Mortality and causes of death

Life expectancy at birth is 53 and 55 years for males and women respectively. The infant mortality rate (children under one year old) is 90/1000 live births. For children under 5, the death rate is 146/1,000 live births. The maternal mortality rate is 980/100,000 live births5 .

For diseases, the top 10 causes of death in Guinea are :

	Illness
1	Hemorrhages during childbirth
2	Mechanical dystocia
3	Malaria
4	Acute anemia
5	Myocardial infarction
6	Trauma
7	Severe dehydration
8	Acute respiratory failure
9	HIV/AIDS
10	Others

For diseases, the top 10 causes of morbidity in Guinea are

	Diseases
1	Malaria
2	Labor dystocia
3	Anemia
4	Trauma
5	Hernias
6	High Blood Pressure
7	Appendicitis
8	Gynecological infections
9	Pneumonia
10	HIV/AIDS

Main reference documents :

- Demographic and Health Survey, Guinea, 2005.
- Global Health Observatory / WHO, 2009.
- World Health Statistics 2010.

SECTION 2 - HEALTH SERVICES

This section provides information on health expenditures and resources for health in Guinea. It presents the contributions of the public sector and from the private sector to general health expenditure, as well as specific information on pharmaceutical expenditure. There is also data on the human resources for health and for the pharmaceutical sector.

2.1 Health expenditure

In Guinea, total health expenditure in 2008 was 1,234,993 billion GNF (Guinean Franc) (224 million US$)6 . Total annual health expenditure represented 5.52% of GDP. Per capita, they were 122,653 GNF (US$ 22.3)7 .

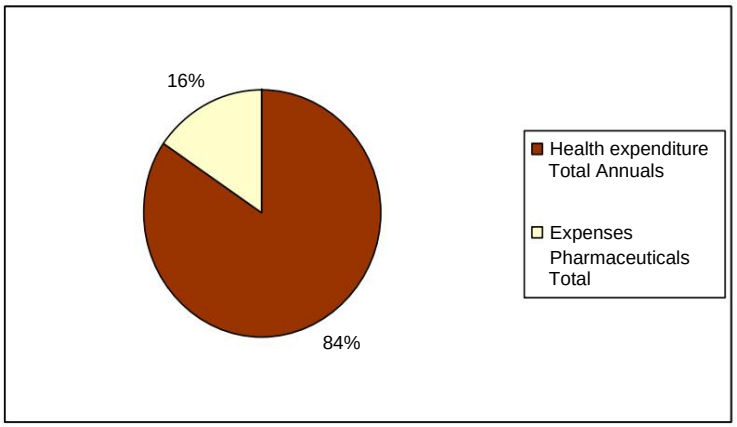
General public expenditure on health (DPGS) in 2008, as shown in the national health accounts (NAH), was GNF 102,053 million (US$ 18.6 million), or 8.3% of the total health expenditure, with an annual per capita total of 14,795 GNF (US$ 2.69). Annual public health expenditure represents 2.8% of the total government budget. Private health expenditure covers 91.7% total health expenditure.

Of the entire population, 5% are covered by a public health service, a public health insurance, social security or other health funds and 0.4% are covered by private health insurance.

Total pharmaceutical expenditure in Guinea in 2008 was 227,836 million GNF (41,424 million US$), or per capita 22,627 GNF (US$ 4.11). The total of pharmaceutical expenditure represents 16% of total health expenditure (Figure 1).

[I] ***According to the CNS definition, "public expenditure" means all expenditure made by the public sector: central and local authorities, public insurance funds and parastatal companies.***

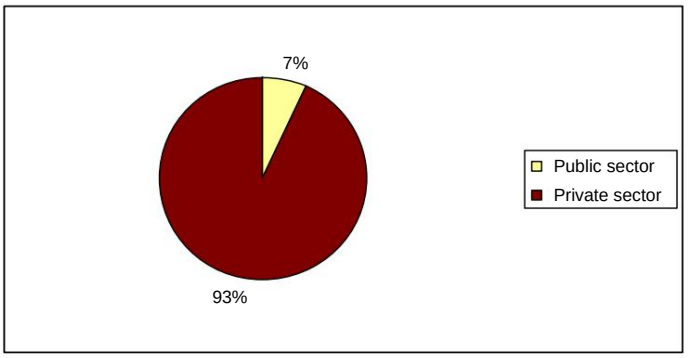
FIGURE 1: Health Expenditure, Guinea, 2008



Public spending on pharmaceuticals accounts for 7% of the total

expenditure for pharmaceutical products (Figure 2), or per capita 1.58 GNF.

FIGURE 2: Share of total pharmaceutical expenditure by sector, Guinea, 2008.



Source: *Report of the National Directorate of Pharmacy and Laboratory*

Total private expenditure on pharmaceuticals is [<number>] million [<national currency>] (US$ [<number>]).

2.2 Health personnel and infrastructure

The table below and Figures 3 and 4 describe the health workforce. 650 ago

(0.91/10,000 inhabitants) licensed pharmacists, of whom 223 (0.31/10,000) work in the

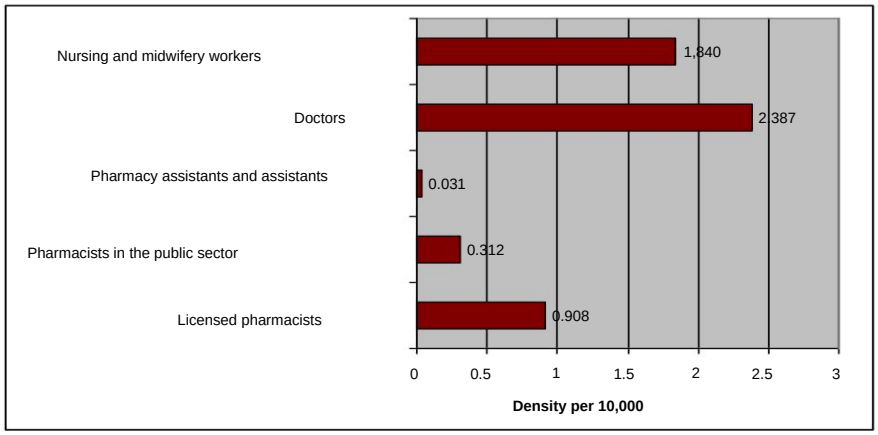
public sector. There are 22 (0.03/10,000) pharmacy assistants and assistants (in all sectors). There are about 30 times fewer assistants than pharmacists.

There are 1,708 (2.38/10,000) doctors and 1,317 (1.84/10,000) nurses and obstetrics in Guinea. The doctor/pharmacist ratio is 2.62 and the ratio doctors/nurses and midwives of 1.29.

Table 1: Human resources for health in Guinea, 2010 (all sectors).

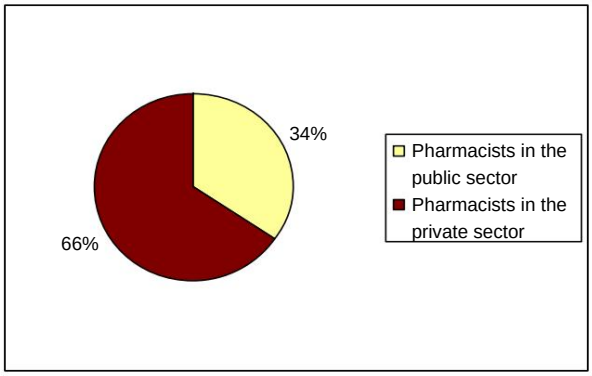
Human ressources	Number	Density for 10000
Licensed pharmacists	650	0.91
Pharmacists in the public sector	223	0.31
Pharmacy assistants and assistants	22	0.03
Doctors	1708	2.38
Nursing and midwifery workers	1317	1.84

Figure 3: Density of health personnel in 2010 in Guinea (all sectors)



Source: *Report from the Pharmacy and Laboratory Department (DNPL), Human Resources Department (DRH) and Guinean Ministry of Health, Global Health Atlas.*

Figure 4: Distribution of pharmaceutical personnel, Guinea, 2011.



Source: *Report from the Pharmacy and Laboratory Department (DNPL), Human Resources Department (DRH) and Guinean Ministry of Health.*

In Guinea there is no strategic plan for the development of human resources in the pharmaceutical sector8 .

The health infrastructures are described in Table 2. There are 42 hospitals 3 beds of hospitals per 10,000 inhabitants in Guinea. There are 1030 health care units and centers primary health and 3 licensed pharmacies.

Table 2: Statistics on health centers and hospitals

Infrastructure	
Hospitals	42
Hospital beds (per 10,000)	3
Primary health care units and centers	1,030
Approved pharmacies	379

The annual starting salary for newly enrolled pharmacists in the public sector is 10 million GNF. The total number of pharmacists who graduated (first degree) in the last two years is 230. The training program in pharmacies is regularly reviewed.

Main reference documents :

- Study and Training Statistics Service (SSEI), Guinea, 2010.

SECTION 3 - POLITICAL ASPECTS

This section focuses on the main characteristics of the pharmaceutical policy in Guinea. The main elements of national drug policies are excerpts from the WHO publication “How to develop and implement a national drug policy” (http://apps.who.int/medicinedocs/en/d/Js5409f/). It also provides information on the manufacturing capabilities of medicines and the legal provisions relating to patents.

3.1 Policy framework

In Guinea, there is a national health policy (PNS)9 . It was updated in 1997. There is also an associated plan for the implementation of the national health policy written in 200410. The National Health Development Plan (PNDS) covers the period 2005-2014.

In Guinea, i, there is an official document on the national pharmaceutical policy11 . It was updated in 2007. There is also an implementation plan for the PPN whose the most recent update dates from the year 1992. Currently, there is a policy on pharmaceuticals (see details in Table 3). The implementation of the pharmaceutical policy is not regularly evaluated.

Table 3: Coverage of PPN12

Political aspects	Blanket
Selection of essential drugs	YES
Drug financing	YES
Drug prices	YES
Drug purchases	YES
Distribution of drugs	YES
Pharmaceutical regulations	YES
Pharmacovigilance	NO
Rational use of medicines	YES

Human Resources Development	YES
Research	YES
Monitoring and evaluation	YES
Traditional medicine	YES

There is a group of policies on medical analysis laboratories which were last updated in 200913 . There is no associated implementation plan to the policy on medical analysis laboratories. Access to essential medicines/technologies, as part of the realization of the right to health, is recognized in the national constitution or legislation14 . There are official written guidelines on drug donations15 .

There is a national policy on good governance in Guinea.
There is a policy for managing and sanctioning conflict of interest issues in the pharmaceutical sector (Law L94/012/CTRN/ articles 22 and 101). There is no code official conduct for public officials. There is no mechanism for denunciation of abuse allowing anyone to draw attention to reprehensible acts in the pharmaceutical sector in Guinea16 .

Main reference documents :

- Ministerial Instruction No. 1707 / MSP 1998.
- National Constitution 2009.

SECTION 4 – TRADE AND PRODUCTION OF MEDICINES

4.1 Intellectual Property Laws and Medicines

Guinea is a member of the World Trade Organization [17]. There are legal provisions for granting patents to manufacturers. They cover the pharmaceuticals and medical equipment

The Industrial Property Service (SPI) of the Ministry of Industry manages the rights intellectual property and ensure that they are respected.
National legislation has been amended to implement the TRIPS Agreement and provides specific flexibilities and safeguards provided under the TRIPS Agreement[18], as presented in Table 4. Guinea fulfills the conditions required for the transition period until 2016.

Table 4: Flexibilities and safeguards provided under the Agreement on TRIPS present in national legislation

Flexibilities and safeguards	Included
Provisions for compulsory licensing applicable for health reasons public	YES
Bolarii Layout	YES

The country has engaged in capacity building initiatives to manage and apply intellectual property rights in order to contribute to innovation and promote public health.

[ii] ***Many countries use this provision of the TRIPS Agreement to advance science and technology. It allows researchers to use a patented invention for research, so as to understand the invention in question more completely.***
In addition, some countries allow generic drug manufacturers to use the patented invention to obtain marketing approval (for example, from public health authorities) without the permission of the patent holder and before the patent protection does not expire. Generic drug producers can then market their products as soon as the patent expires. This provision is sometimes referred to as the "regulatory exception" or the "Bolar" provision.
Article
30 This point has been confirmed in a decision relating to a dispute submitted to the WTO, as being in conformity with the TRIPS Agreement. In its report adopted on April 7, 2000, a WTO dispute settlement panel said Canadian law complied with the TRIPS Agreement by allowing manufacturers to do so . (The case is called "Canada — Patent Protection for Pharmaceutical Products".) [In : WTO WTO Fact Sheet: The TRIPS Agreement and Pharmaceutical Patents, available online at: http:// www.wto.org/ french/ tratop_f/ trips_f/ tripsfactsheet_pharma_2006_f.pdf]

They include legal provisions for data exclusivity, products

pharmaceuticals, patent extension and patent status and marketing authorizations19 .

4.2 Manufacturing

There is 1 licensed manufacturer of pharmaceutical products in Guinea. The only unit

industrial company holding a manufacturing license is called SODONG PHARMA GUI,

it was born from the rehabilitation of the national pharmaceutical company ENIPHARGUI

with Chinese economic operators.

Table 5 below shows manufacturing capabilities.

Table 5: Manufacturing capacities in Guinea.

Manufacturing Capabilities	
Research and Development for the discovery of new active ingredients	YES
Production of pharmaceutical raw materials	NO
Production of dosage forms from pharmaceutical raw materials	YES
Repackaging of finished dosage forms	YES

For the research and development of new active ingredients in Guinea there is

the Center for Research and Valorization of Medicinal Plants of Dubréka.

Main reference documents :

- National Directorate of Pharmacy and Laboratory 2007.
- WHO Level 1, 2007.

SECTION 5 – PHARMACEUTICAL REGULATIONS

This section describes in detail the pharmaceutical regulatory framework, the resources, governing bodies and practices in Guinea.

5.1 Regulatory framework

In Guinea, there are legal provisions establishing the powers and responsibilities of the Pharmaceutical Regulatory Authority (ARP).
The ARP is part of the Ministry of Health and performs a number of functions described in Table 6. The ARP does not have its own website.

Table 6: Functions of the national ARP20

Function	
Marketing authorization / registration	YES
Inspection	YES
Import control	YES
Licensing	YES
Market control	YES
Quality Control	YES
Promotion, advertising for drugs	YES
Control of clinical trials	NO
Pharmacovigilance	YES

In 2011, there were 23 permanent employees at the ARP. The ARP sometimes benefits from occasional support from certain partners (such as: WHO, UNFPA and UNICEF). It is external technical assistance that supports the ARP in its activities. The ARP participates in harmonization/collaboration initiatives, for example it participates in regional workshops organized by WAHO (Organisation Ouest African Health). An assessment of the pharmaceutical regulatory system did not not been made in the last five years. The ARP is financed from the budget ordinary government, as well as other sources such as: WHO, UNFPA, UNICEF. The Regulatory Authority retains the revenues it derives from its activities.

This organization uses a computerized information management system to keep and find information on the various procedures, records, inspections, etc.21

5.2 Marketing Authorization (Registration)

In Guinea, the legal provisions require the issuance of a marketing authorization (registration) for all pharmaceutical products marketed regardless of the exceptions/ exemptions that exist at this level22. There are mutual recognition mechanisms23. There are explicit, accessible criteria
to the public, for the assessment of applications for marketing authorization for pharmaceutical products [24] . In 2011, there were 2,233 pharmaceutical products registered in Guinea. There are legal provisions requiring the ARP to publish the list of registered pharmaceutical products and keep it regularly updated. This Register is updated annually. Medications are always listed under their INN (international nonproprietary name) or under the brand name + INN. The legal provisions impose the payment of a fee for the issuance of market authorizations for medicinal products (registration) based on applications25 .

5.3 Regulatory inspection

In Guinea, there are legal provisions for the appointment of inspectors government in pharmacy. There are legal provisions allowing inspectors to inspect premises where pharmaceutical activities take place; those inspections are required by law and are a prerequisite for the approval of public and private establishments. When these inspections are a legal obligation, they are the same for public and private establishments. Inspections are made in a number of entities listed in Table 7.

Table 7: Local entities inspected to verify GMP compliance

Entity	Inspection
Local manufacturers	YES
Private wholesalers	YES
Retail distributors	YES
Pharmacies and public warehouses	YES
Pharmacies and dispensing points for health facilities	YES

5.4 Import Control

There are legal provisions requiring import authorization for medications. There is legislation allowing sampling of imported products to analyze them.

There are legal provisions requiring the transit of drugs imported through authorized ports of entry. There are regulations or laws allowing the inspection of imported pharmaceuticals at authorized ports of entry26 .

5.5 Approval

In Guinea, there are legal provisions requiring manufacturers to be approved27 .

There are also legal provisions requiring manufacturers (national and international standards) to comply with good manufacturing practices (GMP), even if they are not published by the government.

There are legal provisions requiring importers, wholesalers and distributors to be approved. As there are legal provisions requiring wholesalers and distributors to follow good distribution practices.

Table 8: Legal provisions relating to approvals

Entities requiring authorization	
Importers	YES
Wholesalers	YES
Distributors	YES

The government does not publish good distribution practices.
All pharmacists are required by law to be licensed. There are provisions
legal requirements for private and public pharmacies to be licensed. the
government publishes a National Guideline on Good Pharmacy Practices. The
there is no legal requirement to publish a list of all approved pharmaceutical establishments.

5.6 Market Control and Quality Control

In Guinea, there are legal provisions for market control
pharmaceutical. There is a laboratory in Guinea for the control analyzes of the
quality.
This laboratory is an operational unit of the ARP. The regulatory authority under
also deals with some services elsewhere. The DNPL sometimes cooperates with the Center
Humanitarian Medico-Pharmaceutical (CHMP) in Clermont-Ferrand (in France) for the
control of certain products.

The collaboration of existing national laboratory establishments with the
WHO prequalification program has been accepted. Medications are analyzed
for a number of reasons, summarized in Table 9.

Table 9: Medication Analysis Reasons

Drugs analyzed:	
For quality control in the public sector[iii]	YES
For quality control in the private sector[iv]	YES
When there are complaints or problems are reported	YES
For product registration	YES
For screening for public purchase	YES
For public program products prior to their acceptance and/or distribution	NO

[iii] ***Routine sampling in pharmaceutical warehouses and healthcare facilities***
[iv] ***Routine sampling in retail outlets***

Samples are collected by government inspectors for testing as part of post-marketing surveillance28 .

In the past 2 years, 86 samples have been taken for control analyzes quality. Of the total analyzed, 19 (or 22%) did not meet quality standards. The results are publicly available.

5.7 Drug promotion and advertising

In Guinea, there are legal provisions controlling promotion and advertising for prescription drugs. The DNPL is responsible for regulating the promotion and/or advertising for medicines. Direct advertising for prescription drugs from the general public is prohibited by provisions legal and pre-approval of advertisements or promotional materials for medication is required. There are no guidelines or regulations on the promotion and advertising of non-prescription drugs. There isn't one national code of conduct for drug promotion and advertising from marketing authorization holders.

5.8 Clinical trials

In Guinea, there are no legal provisions requiring authorization to be obtained with the ARP to carry out clinical trials. There are additional laws requiring Obtain approval from an ethics committee or institutional review board for clinical trials to be done.

There are **5.9 Controlled Drugs**

Guinea-Conakry is a signatory to a number of international conventions specified in Table 10.

Table 10: International conventions to which [Country X] is a signatory29

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

There are laws for the control of narcotics, psychotropic substances and precursors.30 .

Fentanyl	
Phenobarbital	

5.10 Pharmacovigilance

In Guinea, there are legal provisions in the pharmaceutical legislation providing for pharmacovigilance activities within the scope of the ARP's mandate. He there are no legal provisions requiring the holder of a marketing authorization on the market to continuously monitor the safety of its products and to make compared to the ARP. There are no laws on monitoring the adverse effects of drugs in Guinea. There is no national pharmacovigilance center in liaison with the ARP.

An official standardized form for reporting adverse events is used in Guinea. Information on adverse events is kept in a national adverse event database.

This database currently contains 40 adverse event reports, 40 of which have been submitted in the past 2 years. These reports are also sent to the WHO Collaborating Center in Uppsala.

There is no national adverse event advisory committee or pharmacovigilance capable of providing technical assistance or causality assessment, risk assessment, risk management, case investigation and,

where applicable, crisis management covering communication in Guinea. He does not exist a clear communication strategy in routine and in crisis situations.

Adverse events are monitored by at least one health program public (e.g. tuberculosis, HIV, AIDS).

A number of measures are envisaged to strengthen the system of pharmacovigilance, including:

- Raising the awareness of stakeholders on the importance of pharmacovigilance.
-Elaboration of data collection sheets: these sheets are validated, tested and edited.
-Provision of forms and training of staff in filling them out, in to make its use effective.
-Follow-up of cases of side effects with report during the campaigns of mass vaccination.

Guinea has the prospect of creating a National Pharmacovigilance Center and the establishment of Pharmacovigilance Committees in each of the formations sanitary.

Main reference documents :

- National Directorate of Pharmacy and Laboratory (DNPL) 2010.

SECTION 6 - DRUG FUNDING

This section provides information on funding mechanisms for medicines in Guinea, with coverage by public health insurance and private institutions, the use of user fees for drugs and the existence of public programs providing drugs free of charge. She also discusses policy and regulations that affect pricing and availability drugs (e.g. price control and taxes).

6.1 Coverage and exemptions for drugs

In Guinea, there are concessions for certain groups to benefit from the free medication (see Table 12). In addition, the public health system or social security systems do not provide drugs free of charge for certain conditions (see Table 13).

Table 12: Population groups benefiting from free medicines

Patient groups	Blanket
Patients who cannot afford them	YES
Children under 5 years old	YES
Pregnant women	YES
The elderly	NO

Table 13: Medicines provided free of charge by the public sector

ailments	Blanket
All diseases related to SCI	NO
All non-communicable diseases	NO
Malaria	YES
Tuberculosis	YES
Sexually transmitted infections	NO
HIV/AIDS	YES
Expanded Program on Immunization (EPI) Vaccines for Children	YES
Others – (Caesarean kit, Anti-leprosy, Ivermectin, Vitamin A, Mebendazol)	YES

Program eligibility criteria are defined at the level of the Ministry of Health.
for patients. Only patients admitted to the programs are supported
for ARV dispensation.
A public health service, public health insurance, social security or
any other form of health insurance at least partially covers drugs.
It covers drugs on the Essential Medicines List (EML) for
hospitalized patients and outpatients. Reimbursement rates
vary according to the insurance schemes (between 70-100%).

Private health insurance systems cover drugs. They are required to
at least partially cover the drugs listed in the EML.

6.2 Financial participation of patients and co-payments

The payment of co-payments or a financial contribution for
consultations is requested at the time of service delivery. Additionally, there are
co-payments or fees to be paid for medication. Income from fees or sale of drugs is used to pay
salaries or supplement income
public health staff in the same facility. Payments are made
per fixed price or in broken tariffs according to the level of the health structure. For Centers
of Health, the package includes consultation and medication. There are also
price discrimination between "child" and "adult". Cost recovery is
instituted for primary health care since 1988. Revenues are used to guarantee the
operation of the health facility. Provision is made for the payment of staff performance
bonuses.32

6.3 Price regulation for the private sectorv In Guinea,
there are legal or regulatory provisions influencing the price of medicines33 .

[v] ***This section does not include information about the voluntary nonprofit sector.***

These provisions apply to wholesalers and retailers without mentioning the generics. However, other subsequent provisions refer to medicines social (medicines for preventive use and medicines intended for the treatment of chronic and/or disabling diseases). Margins have been reduced for these medications.

The government has not put in place an active national monitoring system for retail drug prices. There are regulations requiring that information on retail drug prices be made available to the public34 .

6.4 Price, availability and affordability of essential medicines

The WHO/HAI price survey was not conducted in Guinea. That's why this section does not include elements providing information on the availability, accessibility finance and drug prices.

6.6 Duties and taxes on pharmaceutical products (market)

Guinea does not impose duties on imported active pharmaceutical ingredients (APIs) nor on imported finished products. Value added tax or other taxes are imposed on finished pharmaceutical products. There are provisions for tax exemptions or exemptions for pharmaceutical and health products35 .

Main reference documents :

- Manual of procedures of the Central Pharmacy of Guinea (PCG) 2006.

SECTION 7 - PURCHASING AND DISTRIBUTION OF PHARMACEUTICAL PRODUCTS IN THE PUBLIC SECTOR

This section gives a brief overview of product procurement and distribution pharmaceuticals in the public sector in Guinea.

7.1 Public Sector Procurement

In Guinea, purchasing is both centralized and decentralized. The public sector is supplied by the Central Pharmacy of Guinea (PCG) and partners who support specific health programs.
Public sector purchases are centralized under the responsibility of a purchasing body which is autonomous36 .

Public sector tender documents are publicly available. The public sector award decisions for tenders are also accessible to the public. Purchases are based on prequalification of suppliers.

7.2 Distribution in the public sector

The public supply department in Guinea has a central store of medical supplies at the national level called Central Pharmacy of Guinea (PCG)37. There are 5 public warehouses at the secondary distribution level in the public sector. There are national guidelines on Good Distribution Practices (GDP). There is no body responsible for issuing approvals for BPDs38 .

	YES
	YES
	YES
	YES
	YES

	YES
	YES
	YES

There are routine procedures for tracking the expiry dates of MCM drugs. The MCM is not ISO certified; public warehouses at secondary are not, public warehouses at the secondary level are not GDP certified by an accrediting body.

The PCG does not systematically order all the drugs on the list national essential drugs; but according to customer needs. The PCG infrastructures have been designed taking into account the criteria of good distribution practice. However, no special certificate of GDP compliance for any of its facilities.

7.3 Distribution in the private sector

There are legal provisions for the licensing of wholesalers and distributors in the private sector. There is a list of GDP certified wholesalers and distributors in the private sector39 .

Main reference documents :

- National Directorate of Pharmacy and Laboratory (DNPL) 2010.
- Pharmaceutical law n°94/012/CTRN of March 22, 1994 (known as "Law L / 012")

SECTION 8 - SELECTION AND RATIONAL USE OF MEDICINES

This section discusses the structures and policies governing the selection of essential drugs and the promotion of the rational use of drugs in Guinea.

8.1 National structures

There is a National Essential Medicines List (EML).
The EML was last updated in 2006 and is not accessible to audience.

There are currently 202 drugs in the EML. The selection of drugs for the LME is not done through a written process. A mechanism aligning the EML with standard treatment guidelines is in place40 .

National standardized treatment guides for the most common diseases are approved by the Ministry of Health in Guinea.
They were last updated in 2005. The specific guides cover [the primary care (updated in 1988), secondary care and pediatric conditions (the latter two updated in 2005)]41 .

Of all public health facilities, 66.5% have a copy of the LME. [42]

There is no public or independently funded national information center informing prescribers, dispensers and consumers about the medications. Public education campaigns on topics related to rational use of medicines have not been organized for the past two years.
A survey on the rational use of medicines was not carried out on these two last years. There is no national program or committee, in which the government, civil society and professional bodies, to monitor and

promote the rational use of medicines. A written national strategy for stemming antimicrobial resistance does not exist.

8.2 Limitation

There are legal provisions governing the licensing and practices of prescribers. In addition, there are legal provisions limiting the issuance of drugs by prescribers. In the private sector, prescribers dispense drugs43 .

There are regulations requiring hospitals to organise/establish Pharmaceutical and Therapeutics Committees (DTCs).
When there is an obligation to have CPTs, there is one in more than half of the referral facilities, general hospitals and regions/provinces.

The physician training program has a number of elements of base described in Table 16.

Table 16: Basic aspects of the medical training program

Program	Covered
The concept of the LME	YES
The use of standardized treatment guides	YES
Pharmacovigilance	NO
Problem-solving drug therapy	NO

Mandatory continuing education covering pharmaceutical issues is required for doctors but not for nurses or paramedics.

Prescription by the DCI is mandatory in the public sector. On all of patients treated in public outpatient services, 59.7% receive antibiotics.

8.3 Dispensing of medication

In Guinea, there are legal provisions governing the dispensing of medicines by pharmaceutical staff. The basic training program for pharmacists includes a range of items such as those described in Table 18.

Table 18: Basic Aspects of the Pharmacist Education Program

The concept of the LME	YES
The use of standardized treatment guides	YES
Pharmacovigilance	YES
Problem-solving drug therapy	YES

Compulsory continuing education covering the rational use of medicines is not not required for pharmacists.

Substitution with equivalent generic drugs at the time of dispensing is not permitted in public or private sector facilities44 . The antibiotics are sometimes sold without a prescription. Injectable drugs are sometimes sold without a prescription.

Main reference documents :

- WHO Level 1, 2007.

SECTION 9 - HOUSEHOLD / ACCESS DATA

This section does not present data on household surveys made in the past in Guinea, therefore, real access to medicines for normal and poor income households were not provided.

List of main reference documents :

[1] World Health Organization (WHO) (2010), “World Health Statistics 2010”, Editions of WHO, Geneva. Available online: http://www.who.int/whosis/whostat/2010/fr/index.html

[2] World Health Organization (WHO) (2010), “World Health Statistics 2010”, Editions of WHO, Geneva. Available online: http://www.who.int/whosis/whostat/2009/fr/index.html

[3] WHO/ Global Health Observatory 2009.

[4] Ministry Macroeconomic Framework Plan 2010.

[5] World Health Statistics 2008 // Demographic and Health Survey, Guinea - 2005.

[6] Guinea National Health Accounts, 2008.

[7] Calculation based on data provided in "National Health Accounts" Guinea, 2009.

[8] Human Resources Department (DRH) / Ministry of Health and Public Hygiene (MSHP) 2010.

[9] Ministry of Health and Public Hygiene (MSHP)1997.

[10] MSHP 2004.

[11] DNPL/MSHP 2007.

12 DNPL/MSHP 1992.

13 DNPL/MSHP 2009.

[14] National Constitution 2009.

[15] Ministerial Instruction No. 1707/MSP 1998.

16 Law 02/CTRN / Articles 22 and 101 of 1994.

17 WTO 1995.

[18] Law L2001 / 007 of 11/06/2001.

[19] WHO Level 1, 2007.

20 Decree D 92/PRG of 26 May 1992.

[21] DNPL 2011.

22 Order No. 3756 / MSPP/ CAB/ 90 of June 6, 1990.

[23] DNPL 1998.

[24] Order No. 4901 / MSP of November 2, 2000.

[25] DNPL 1991.

[26] DNPL 1999.

[27] Pharmaceutical Law No. 94/012/CTRN of March 22, 1994 (known as "Law L / 012").

[28] National Laboratory for the Quality Control of Medicines (LNCQM) 2010.

[29] International Narcotics Control Board 1990.

[30] Law L/012 (Section 8) 1994.

[31] DNPL 2010.

[32] MSHP 1998.

[33] Joint Order No. 8486/MC/MSP/ of 09/09/1985 fixing the price structure of products and specialties Pharmaceuticals, 1985.

[34] WHO Level 1, 2007.

[35] Order No. 001126/MEF/CAB of January 31, 2005.

[36] Central Pharmacy of Guinea (PCG), 2006.

[37] PCG 1992.

[38] PCG/ Manual of procedures 2006.

[39] DNPL 2011.

[40] Order No. 2778/MSP/CAB, 2006.

[41] Ministry of Health 2008.

[42] WHO: Rational use of medicines database, 2002.

[43] WHO Level 1, 2007.

[44] Decree 94/043 (Article R23), 1994.

Profile of the Pharmaceutical Sector of

Country

GUINEA

Pharmaceutical Sector Country Profile Survey

1. Background and Rationale

The Pharmaceutical Sector Country Profiles aim to improve the availability of quality information on the structures, processes and outcomes of the health and pharmaceutical sectors of countries. This information is collected through a questionnaire and is available in country, regional and global databases and reports for use in countries by policy makers, health and pharmaceutical experts, international partners and by the public.

The information is categorized into nine sections, namely: (1) health and demographic data, (2) Health Services, (3) Medicines Policy, (4) Medicines Trade and Production, (5) Medicine Regulation, (6) Medicine Financing, (7) Pharmaceutical Procurement and Distribution (8), Selection and Rational Use and (9) Household Data and Access.

Since 1999 and every four years, health officials from the 193 Member States have been asked to complete a standardized questionnaire (called Level I) on the state of the national pharmaceutical situation. Level I Indicators assessed the structures and processes related to a country's pharmaceutical situation. They were used to perform a rapid assessment that would highlight the strengths and weaknesses of the countries pharmaceutical sector. 156 countries responded to the 2007 Level I survey, and the results are available in a WHO database, in a global report as well as in a number of the regional reports eg. Caribbean, Pacific. The attached Country Pharmaceutical Sector Profile Questionnaire will replace the Tier I tool for the 2011 survey. I and improving the quality and type of information (for example, results indicators have been added) and country ownership. The new tool was piloted in the 15 countries of the Southern African Development Community (SADC) in 2009 and in 13 countries around the world in 2010. The results of these studies are available online at the following address : 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. During 2010, the two organizations came to an agreement on the indicators to be included in the Pharmaceutical Sector Country Profile questionnaire and on the joint undertaking of data collection in the countries. In 2009, the Global Fund developed and introduced Country Profiles for Pharmaceuticals and Health Products Management ("PHPM") to gradually replace the Procurement and Management Plan ("PSM"). The information collected in the Pharmaceutical Sector Country Profile questionnaire will be used by the Global Fund during its grant negotiations and will also support grant implementation. In addition to this country profile which provides an overview of the pharmaceutical sector in the country, the Global Fund will also use a second questionnaire which is specific to it and which will focus on medicine procurement and supply.

2. What do the Pharmaceutical Sector Country Profiles offer?

Completing this questionnaire will probably take your time, but it will be very useful to do so. Your country and your partners will benefit in a number of ways and as follows:

1) The questionnaire is a unique opportunity to consolidate in one place information that is available in different places and institutions, e.g. National Medicines Regulatory Authority, Central Medical Supply, National Health Accounts , etc.

2) The method proposed for completing the questionnaire ensures that the data collected is of good quality and that the source and date of the information are known and mentioned.

3) Data on the structure, processes and results of the pharmaceutical sector are collected. The questionnaire was pre-populated with data available in the public domain; the indicators are divided into essential indicators and complementary indicators in order to more easily identify what is more important.

4) The data collected will be analyzed and a narrative report that summarizes the drug situation in the country will be produced.

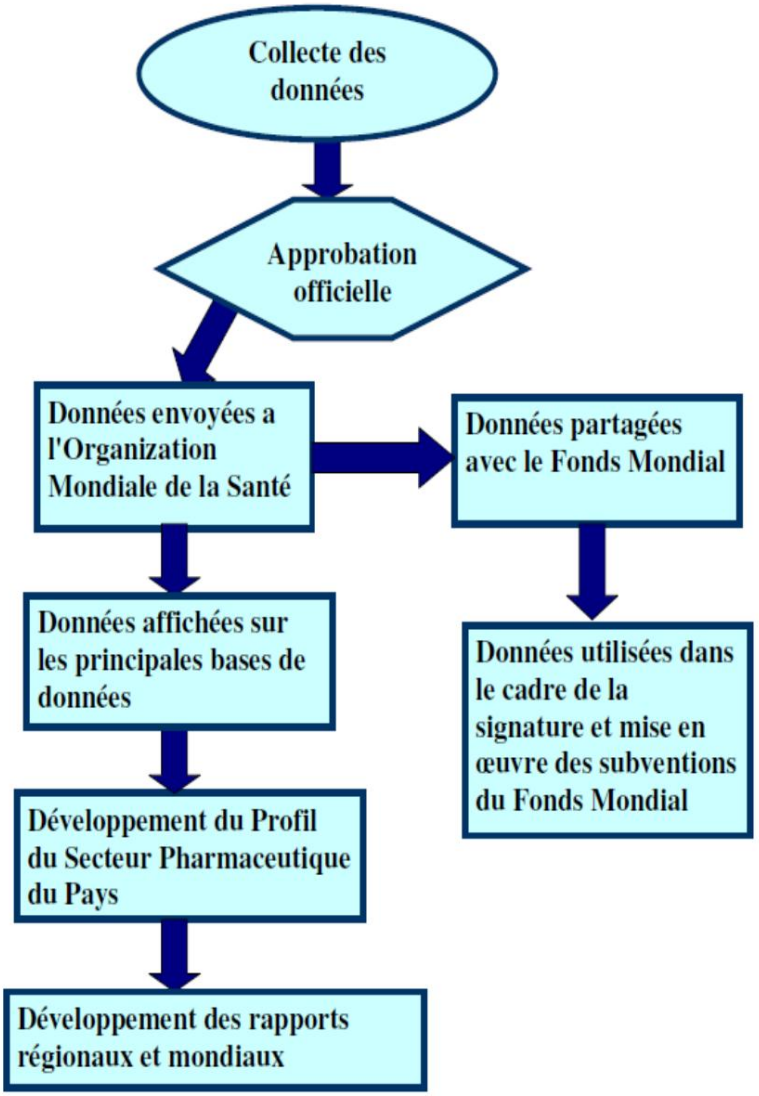
5) The collected data can be transformed into a narrative report with a solid analysis of the data and bibliographical references, which summarizes the situation of medicines in the country.

6) Based on the experiences of previous surveys, a glossary including the most important definitions and a user manual for the questionnaire have been produced and are appended to the questionnaire.

3. The process of collecting data and analyzing the results

3.1 Data collection. This questionnaire for the Country Pharmaceutical Sector Profile has already been completed with reliable data available from available sources at global and national level. We now ask you to review, correct (if necessary) and validate the information already included in the questionnaire and fill in the gaps based on reliable information available in your country.

To do this, we recommend that you identify the most appropriate experts and institutions to answer the various questions making up the tool so that the questionnaire is completed within the time limit with quality information. If during the data collection process, clarification is needed, WHO regional offices and headquarters can provide the necessary assistance and support.



3.2 Official Approval. Once the questionnaire has been completed, the information it contains must be officially approved and their disclosure authorized by a senior official of the Ministry of Health. This will be done by signing the attached form which contains the official approval of the questionnaire. This will ensure that the quality of the information contained in the Pharmaceutical Sector Profile questionnaire of the country is certified by the country.

3.3 Data shared with the Global Fund. Data collected from priority countries for the Fund Mondial will be shared with the Global Fund and they will be used as part of the signature and implementation of Global Fund grants.

3.4 Data displayed on major databases. Country-approved data will be posted on health databases (such as the WHO Global Health Observatory, http://www.who.int/gho/en/), to make them accessible policy makers, researchers, health and medicine experts, international partners and the public.

3.5 Development of the Country Pharmaceutical Sector Profile. The data contained in the questionnaire can be used by the country to develop a narrative profile that illustrates the situation of the pharmaceutical sector in the country. To do this, WHO has prepared a template for the narrative report (included on the CD) which can be easily used by countries and will help to present the data.

in the form of text, tables and graphics. At the request of the country, the development of the narrative profile can also be carried out by WHO. The country will have copyright to the narrative report and may publish it as a national document.

3.6 The development of regional and global reports. The information provided by the countries will be analyzed by WHO and used to produce regional and global reports on the situation of the pharmaceutical sector of the countries in 2011. These reports will give an overview of the progress made between 2007 and 2011, the challenges that remain solve and will include analysis of data by technical areas, by country income level and by geographic location.

Guidelines for Completing the Country Pharmaceutical Profile Questionnaire

Questionnaire Please read all instructions carefully before completing this instrument.

1. Macros: the instrument has macros installed. A macro is a series of MS Word commands and instructions that are combined into a single command to accomplish a task automatically.
In order for these macros to work properly, the MS Word macro security level on your computer must be set to "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 "Security Level" tab.
4. Set security to "low" and click ok.

After refilling the instrument, the setting should be reset to a higher level of security to protect your computer.

2. Basic and supplementary indicators: the apparatus consists of basic questions and supplementary questions. Basic questions cover the most important information, while supplemental questions cover more specific information applicable to specific sections. Please note that the basic questions have been shaded in different colors for the different sections of the instrument, while the additional questions are all white.

This should help you distinguish between different categories of indicators. Please try to complete all the basic questions for each section before moving on to the additional ones.
Remember that we only ask you to collect information that is already available and that you are not required to carry out any further investigation(s).

3. Pre-filled data: the answers to some of the questions have been pre-filled by WHO. If so, please verify this information as it may not be up to date. If you find that

one of the pre-filled answers is not correct, please change the value and indicate the source and year.

4. Calculated fields: for some indicators, you will not be required to enter the value as these will be automatically generated, at WHO Headquarters, using data entered in related fields. These fields have been clearly marked in red - please do not enter data in their places or modify data that is already in this field. For example, per capita health expenditure will be automatically calculated once total health expenditure and the number of inhabitants are entered into the questionnaire. This system is intended to improve the quality of the answers and avoid you having to perform additional calculations. Calculated fields are protected and cannot be changed.

5. Possible answers:
'Yes/ No/ Unknown' checkboxes: tick one of the three options (only one answer possible).
Multiple-choice checkboxes: tick all the options that apply (several answers possible).

Percentage fields: 0-100. Please use a "period" for decimals (example: 98.11).
Do not use forks. If you only have ranges, use the median or mean. You can always indicate the range in the comment boxes.
Number fields : Unlimited numbers. Please use a "period" for decimals (example: 29387.93). Do not use forks. If you only have ranges, use the median or mean. You can always indicate the range in the comment boxes.

6. Comments: Comments fields allow free text entry to clarify or follow up on answers given. Please put references in each comment using the number of the question you are talking about (eg: 2.01.02).

7. Year of data: the years fields should be used to specify the year of the data used to answer the question (1930-2011 possible). Please use this column as follows:

- When the source refers directly to a specific document (for example: "Medicines Act" or "EML"), please put the year of publication of the document (note: only the year and not a specific date cannot be entered).
- When the source refers to a document that contains more data than the document itself, please include the year of origin 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, please put the current year.

8. Source of data: The sources used for the answers given will be referenced in the country profile. Please specify your sources as clearly as possible by indicating the Name, year, and author/publisher of the documents used. Also indicate, if applicable, an Internet link to the documents. If the available reference does not exist in French, cite it, whatever the language. Use the 'source' column to enter the Name and year of the **source,** and use the "Comments and Bibliographic References" fields at the end of each section to list the sources. In the absence of reference documents, indicate the name and title of the person and/or entity employing him as the source of information. Examples are given below:

Harmonized questionnaire on the national pharmaceutical sector			**Year**	**Source**
7.01.02	There is a National Essential Medicines List (EML)	Yes ÿ No ÿ Unknown	2009	LME 2009
7.01.02.01	If yes, Number of drugs included in the list	400	2009	LME 2009
7.01.03	% (mean) of public health facilities with a copy of the list – survey data	55	2005	Access to medicines and use of medicines in COUNTRIES, 2009
7.01.04	The selection of products included in the national list exists falls under an official committee or equivalent structure	Yes ÿ No ÿ Unknown	2011	Ministry of Health, responsible for public health
7.01.05	Comments and Bibliographical references	*Access to medicines and use of medicines in COUNTRIES: WHO level II facility survey.* Ministry of Health, published in 2009 Document available at: www.moh.ch/docu/level2survey *List of essential drugs COUNTRY.* Ministry of Health 2009 John de Groot, public health officer. COUNTRY Ministry of Health		

9. Documents: You will see in the instrument that we ask you to collect and provide us with a number of key national documents which we believe will greatly enhance the profile when published on the web. These are the following documents that We invite you to attach, if applicable:

- National Pharmaceutical Policy (NPP)
- PPN implementation plan
- National pharmaceutical legislation
- Report or national strategic plan on human resources in the pharmaceutical field

- Most recent national pharmaceutical market report (regardless of source)
- Report from the national pharmacovigilance center (including an analysis report on the effects adverse drug reactions for the past two years)

- National drug regulatory legislation - Annual report of quality control laboratories - Annual report of the national regulatory authority - Legal provisions relating to the regulation of drug prices - Drug procurement policy - National list of essential medicines (EML)

- National Standard Therapeutic Guides (GTN)
- National Antimicrobial Resistance Strategy - All medicine price/availability surveys, household surveys, and rational use surveys other than those used to pre-populate the instrument.

The main documents to be attached are listed in a table on the last page of the questionnaire.
Indicate for each of them the exact title, the publisher and the year. See the example below:

Document	exact title	Author	Editor	Year File	
List of drugs essentials	National Drug List	Ministry of Health	Ministry of Health	2009	LME.doc
National drug policy	National drug policy	Federal Ministry health	Federal ministry health	2005	NDP.doc

These documents will be published on the WHO website, in the pharmaceutical library, but their publication must be authorized by the Ministry of Health. You can send us these documents by email, as an attachment, but you can also upload them to a secure site. Please use the table at the end of this instrument to enter the Name, Year and Author of the attached documents

10. Attach files to instrument: Please group all files to be attached in the same folder on your computer. Give a Name to the documents as follows: <Short name of >.doc (example: LME.doc). Then compress (ZIP) the files and attach the compressed file to the completed instrument sent by email. If the total size of the compressed file exceeds 7 MB, you can transfer the documents to MedNet, a secure server managed by WHO. Simply address your MedNet access request to Enrico Cinnella (cinnellae@who.int) which will tell you how to transfer files. You can also upload documents to the WHO Medicines Documents server at http://hinfo.humaninfo.ro/medicinedocs/ but the documents will not appear on the Drug Documents site until the beginning of the following month.

11. Manual: The manual contains detailed instructions for the instrument, where to find information and how to answer questions. The manual is located at the end of the questionnaire.

12. Glossary: All essential and/or problematic points of the instrument are defined in the glossary. It is strongly recommended that you use the glossary, as exact definitions may vary by country and institution. The glossary is located at the end of the file.

13. Registrants and Acknowledgements: At the beginning of each section, fields are provided for entering information about the registrant of that particular section. There may also be multiple declarants. At the end of the tool, please add a list of contributors to acknowledge in the foreword of the country profile. Indicate their Name and the main organization(s) they work for.

14. Data Approval: Prior to returning the device to Us, its official approval must be signed by an official from the Ministry of Health. This approval is part of the documents that will have been sent. Please have a senior Ministry of Health official sign the approval to authorize the use and publication of the data.

15. Creating a Country Profile: The data you will collect through this questionnaire can be used to develop a Pharmaceutical Sector Country Profile. Examples of profiles available online at: are http://www.who.int/medicines/areas/coordination/coordination_areas/en/index.html (included in the CD) which can be easily used by countries and which will allow the data collected through the questionnaire to be presented with the help of tables and graphs. Countries can use the generic template provided by WHO and add the information to the questionnaire. Below you can find an example of the template which shows how the fields can be modified according to the precise answers provided by each country.

3.2 Intellectual Property Rights and Medicines

Country X is/is not a member of the World Trade Organization. The country has/has not a patent law. National legislation has/has not been amended to implement the TRIPS Agreement. Country X meets/does not meet the eligibility criteria for the transitional period until 2016.

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

Provisions relating to the granting of compulsory licenses which may be applied for reasons of public health	YES NO

Each section of the questionnaire has comment boxes that you can use to complete the answer to one or more questions. These comments will be included in the profile to present the country situation in more detail and nuance.
In the questionnaire, you are also invited to specify the source of each information provided, and this to enable Us to develop a system of bibliographic references for the profiles.
Once the profile has been established, We will send you a copy that you will want to review and improve. After your review, We will communicate the final version of the profile to the Ministry of Health for authorization to publish it.

Section 0 General Information

0.01 Contact

0.01.01	Country (precoded)	Guinea-RV
0.01.02	Person responsible for the questionnaire	Dr Mory FOFANA and Dr Mariama Siré SANO
0.01.03	Address (street, city)	
0.01.04	Telephone number	(224) 60523644/64215410
0.01.05	Email address	fofanamory52@yahoo.fr/msnsano@yahoo.fr
0.01.06	Web address	
0.01.07	Institution	DNPL/MSHP

Section 1 Health and demographic data

1.00 Registrant Information for Section 1

1.00.01	Name of person responsible for completing this section of the instrument	Mamadou Badian DIALLO, Technical Director of BCR/INS Ministry of Planning
1.00.02	Phone number	(224) 60 29 51 02 / 30 40 38 36
1.00.03	E-mail address	
1.00.04	Other registrants for this section	M'Ballou BERETE (BCR), Oumar BARRY (BCR), Dr Sékou CONDE (DNEHS/Ministry of Health), Sékou DIOUBATE (Head of National Accounting Division/Ministry of Planning)

1.01 Demographic and socio-economic indicators Basic questions

			Year	Source
1.01.01	Total population (.000)	7156.406	1996	GDPR
1.01.02	Population growth rate (annual %)	3.1	1996	GDPR
1.01.03	Total GDP (US$ million)	4533.09	2010	Ministry Plan, Framing macro economic
1.01.04	GDP growth (annual %)	1.9	2010	Ministry Plan Framing macro economic 2010/PRSP
1.01.05C	GDP per capita (current US$ exchange rate)	432.1	2010	Ministry Plan
1.01.06	Comments & bibliographical references	1.0103: the exchange rate was estimated at: 1 USD = 5,500 GNF in 2009; the GDP considered is the nominal GDP.		

Additional Questions

			Year	Source
1.01.07S	Population <15 years (% of total population)	45.6	1996	GDPR
1.01.08S	Population >60 years (% of total population)	7	1996	GDPR
1.01.09S	Urban population (% of total population)	29.9	1996	GDPR
1.01.10S	Total fertility rate (births per woman)	5.7	2005	DHS III
1.01.11S	Population living on less than $1.25/day (PPP) (%)	70.13	2003	World Bank data
1.01.12S	Population living below national poverty line (%)	53	2007	ELEP 2007-2008
1.01.13S	Income share of poorest 20% of population (% of national income)	5.75	2003	World Bank data
1.01.14S	Adult literacy rate, 15+ (% of total population)	34.5	2007	ELEP 2007-2008
1.01.15S	Comments & References bibliographic	1.01.03: The exchange rate for 1 USD= 5,500 GNF 1.01.04: This is the nominal GDP growth rate. 01.14S: Adult literacy rate was considered from age 10		

1.02 Life expectancy, morbidity and causes of death
Basic questions

			Year	Source
1.02.01	Male life expectancy at birth (years)	52.7	1996	GDPR
1.02.02	Life expectancy at birth for females (years)	55.4	1996	GDPR
1.02.03	Infant mortality rate, birth to 1 year (/1,000 live births)	91	2005	DHS III

1.02.04	Under age mortality rate five years (/1,000 live births)	163	2005	DHS III
1.02.05	Maternal mortality rate (/100,000 live births)	980	2005	DHS III
1.02.06	List the top 10 killer diseases	Yes		
1.02.06.01 Illness 1		Hemorrhage of childbirth		
1.02.06.02 Illness 2		Mechanical dystocia		
1.02.06.03 Illness 3		Malaria		
1.02.06.04 Illness 4		Acute anemia		
1.02.06.05 Illness 5		Myocardial infarction		
1.02.06.06 Illness 6		Trauma		
1.02.06.07 Illness 7		Severe dehydration		
1.02.06.08 Illness 8		Acute respiratory failure		
1.02.06.09 Illness 9		HIV/AIDS		
1.02.06.10 Illness 10		Others		
1.02.07	List the top 10 illnesses that cause morbidity	Yes	2010	DNEHS
1.02.07.01 Illness 1		Malaria		
1.02.07.02 Illness 2		Labor dystocia		
1.02.07.03 Illness 3		Anemia		
1.02.07.04 Illness 4		Trauma		
1.02.07.05 Disease 5		Hernia		
1.02.07.06 Illness 6		High blood pressure		
1.02.07.07 Illness 7		Appendicitis		

1.02.07.08 Illness 8		Gynecological infections
1.02.07.09 Illness 9		Pneumonia
1.02.07.10 Illness 10		HIV/AIDS
1.02.08	Comments & bibliographical references	1.02.06 and 1.02.07: These are hospital data

Additional Questions

		Year	Source
1.02.09S Adult mortality rate of both sexes from 15 to 60 years old (/1,000 inhabitants)	14	2005	DHS III
1.02.10S Neonatal mortality rate (/1,000 live births)	39	2005	DHS III
1.02.11S Mortality rate Normalized according to age due to non-communicable diseases (/100,000 inhabitants)	844	2004	WHSurvey
1.02.12S Age -standardized mortality rate due to cardiovascular disease (/100,000 population)	389	2009	WHSurvey
1.02.13S Mortality rate Normalized according to age due to cancer (/ 100,000 inhabitants)	149	2009	WHSurvey
1.02.14S HIV/AIDS mortality rate (/100,000 population)	65	2007	WHStatistics
1.02.15S Death rate for tuberculosis (/100,000 inhabitants)	60	2008	WHSurvey
1.02.16S Mortality rate for malaria (/100,000 inhabitants)	164	2006	WHSurvey
1.02.17S Comments & bibliographical references (to add extra lines in the input field, press <enter>)			

Section 2 Health services

2.00 Registrant Information for Section 2

2.00.01	Name of person responsible for completing this section of the instrument	Olivier Dominique, Financial Affairs Department, Ministry of Health
2.00.02	Phone number	Tel: (00224) 60 55 06 79 OR 62 55 06 79
2.00.03	E-mail address	
2.00.04	Other registrants for this section	Dr Ismael DIALLO (UGAR), Victor SYLLA (Resources Department Humans/MSHP), Dr Karifa DOUNO (DNPL/MSHP), Dr Sékou CONDE (DNEHS/MSHP), Dr Aboubacar SALL (SSEI/MSHP), Dr Soundiata KEITA (Pharmacy Department/FMPOS)

2.01 Health expenditure
Basic questions

			Year	Source
2.01.01.01	Annual health expenditure total (million NCU)	1,234,993	2009	tech mini Guinea NHA WHO
2.01.01.02	Annual health expenditure total (US$ millions)	360.84	2008	NHA data
2.01.02C	Total health expenditure as % of gross domestic product Total annual health			
2.01.03.01C	expenditure per capita (UMN)	168,660.56		
2.01.03.02C	Total annual health expenditure per capita (US$)	19		
2.01.04.01	General Annual Public Health Expenditure (million UMN)	102,053.25	2008	finance law 2008
2.01.04.02	General Annual Public Health Expenditure (millions US$)	39.67	2008	NHA data
2.01.05	Annual public health expenditure as a percentage of budget	2.8	2008	finance law

	total public (% of total public budget)			
2.01.06C	Annual Public Health Expenditure as % of Total Health Expenditure (% of Total Health Expenditure)	10.99	2008	NHA data
2.01.07.01 vs	Annual public health expenditure per capita (UMN)	18,540.09		
2.01.07.02 vs	Annual public health expenditure per capita (US$)	4.03		
2.01.08C	Private Health Expenditure as % of Total Health Expenditure (% of Total Health Expenditure)	8.47	2009	NHA data
2.01.09	Population covered by public health service or public health insurance or other health fund (% of total population)	5	2010	2010 DNEHS Report
2.01.10	Population covered by private health insurance (% of total population)	0.4	2010	DNEHS report
2.01.11.01	Total pharmaceutical expenditure (million UMN)	227.836.041569	2010	DNPL
2.01.11.02	Total pharmaceutical expenditure (US$ million)	34.416320	2010	DNPL
2.01.12.01 vs	Total pharmaceutical expenditure per capita (UMN)	20,782		
2.01.12.02 vs	Total pharmaceutical expenditure per capita (US$)	3		
2.01.13C	Pharmaceutical expenditure as % of GDP (% of GDP)			
2.01.14C	Pharmaceutical expenditure as % of health expenditure (% of total health expenditure)	19		
2.01.15.01	Total public pharmaceutical expenditure (million UMN)	15,947.97	2008	DAF/MSHP
2.01.15.02	Total public pharmaceutical expenditure (US$ million)	3.544	2008	CFO

2.01.16C	Share of public pharmaceutical expenditure as a percentage of total pharmaceutical expenditure (%)			
2.01.17.01 vs	Public pharmaceutical expenditure per capita (UMN)	1,546.3		
2.01.17.02 vs	Public pharmaceutical expenditure per capita (US$)	0.34		
2.01.18.01	Total private pharmaceutical expenditure (million UMN)	211.888.071569	2010	DNPL
2.01.18.02	Total private pharmaceutical expenditure (US$ million)	32.007261	2010	DNPL
2.01.19	Comments & references bibliographic	2.01.091: The National Social Security Fund covers 3% of the total population.		

Additional Questions

			Year	Source
2.01.20S	Social security expenditure as % of public health expenditure (% of public health expenditure)	1.48	2008	NHA data
2.01.21S	Market share of generic [branded and INN] pharmaceutical products by value (%)			
2.01.22S	Annual growth rate of total pharmaceutical market value (%)			
2.01.23S	Generic Pharmaceuticals Market Value YoY Growth Rate (%)			
2.01.24S	Private out-of-pocket expenditure as % of private health expenditure (% of private health expenditure)	99.49	2008	NHA data
2.01.25S	Premiums for private prepaid health plans as % of total private health expenditure (% of private health expenditure)	0.01	2008	NHA data
2.01.26S	Comments & bibliographical references			

2.02 Health workforce and infrastructure Basic questions				
			Year	Source
2.02.01	Total number of pharmacists licensed to practice in your country	650	2010	DNPL Report
2.02.02C	Pharmacists per 10,000 population	0.57		
2.02.03	Total number of pharmacists in the public sector	223	2010	HRD/MSHP
2.02.04	Total number of pharmacy technicians and assistants	22	2005	Global Health Atlas
2.02.05	Is there a strategic plan for the development of human resources in pharmacy in your country?	Yes ☐ No ☒		
2.02.06	Total number of doctors	1,708	2010	HRD/MSHP
2.02.07C	Doctors per 10,000 inhabitants	1.55		
2.02.08	Total number of nursing and midwifery staff	1,317	2010	HRD/MSHP
2.02.09C	Nurses and midwives per 10,000 population	1.2		
2.02.10	Total number of hospitals	42	2011	DNEHS/MSHP
2.02.11	Number of hospital beds per 10,000 inhabitants	3.00	2009	WHSurvey
2.02.12	Total number of primary health care posts and centers	1,030	2010	DNEHS report
2.02.13	Total number of licensed pharmacies	379	2010	DNPL Report
2.02.14	Comments & bibliographical references	2.02.12: The 1,030 primary health structures are distributed as follows: 412 Health Centers and 618 Health Posts 2.02.01: The 650 represent all pharmacists including those in the public and parapublic.		

Additional Questions

			Year	Source
2.02.15S	Newly Graduate Pharmacist Annual Net Starting Salary in the Public Sector – UMN	10,000,000	2010	SSEI
2.02.16S	Total number of pharmacists who obtained their diploma (diploma of	230	2010	Department Pharmacy of the

	basis) in the last two years in your country			Faculty of Medicine
2.02.17S	Are there accreditation criteria for pharmacy schools ?	Yes ☐ No ☐		
2.02.18S	Is the pharmacy study program reviewed regularly ?	Yes ☒ No ☐	2010	Department Pharmacy of the College of Medicine
2.02.19S Comments & References bibliographic		2.02.17S: There is only one school of pharmacy in Guinea, that of the National University 2.02.2.02.16S: The number of graduates breaks down as follows: 75 in 2009 and 155 in 2010 2.0218S: The programs have been harmonized within the framework of WAHO. Entry into force is scheduled for 2013.		

Section 3 Pharmaceutical policies

3.00 Registrant Information for Section 3

			Year	Source
3.00.01	Name of person responsible for completing this section of the instrument	Dr. Harirata BAH		
3.00.02	Phone number	(224) 60 29 70 71		
3.00.03	E-mail address	harirata@yahoo.fr		
3.00.04	Other registrants for this section Abdou	aye Bademba Barry Legal Advisor		

3.01 Policy Outline Basic Questions

			Year	Source
3.01.01	There is a national health policy. If yes, enter the year of the document on most recent in the "year" field	Yes ☒ No ☐	1997	MSHP
3.01.02	There is a national health policy implementation plan. If yes, enter the year of the most recent document in the "year" field	Yes ☒ No ☐	2004	MSHP
3.01.03	Possible comments on the health policy and its implementation plan	3.01.01: There are several other documents from policy according to health programs: Pharmaceutical Policy, Reproductive Health Policy, Primary Health Care Policy, etc. 3.01.02 The National Plan for Health Development (PNDS) covers the period		

		2005-2014		
3.01.04	There is an official document relating to national drug policy. If yes, enter the year of the most recent document in the "year" field	Yes ☒ No ☐	2007	DNPL/MSHP
3.01.05	There is a group of policies regarding pharmaceuticals	Yes ☒ No ☐	1992	DNPL/MSHP
3.01.06	The national drug policy covers the following elements : following :	Yes		
3.01.06.01 Selection of essential drugs		Yes ☒		
3.01.06.02 Drug financing		Yes ☒		
3.01.06.03 Drug prices		Yes ☒		
3.01.06.04 Drug purchases		Yes ☒		
3.01.06.05 Distribution of medication		Yes ☒		
3.01.06.06 Pharmaceutical regulations		Yes ☒		
3.01.06.07 Pharmacovigilance		Yes ☐		
3.01.06.08 Rational use of medicines		Yes ☒		
3.01.06.09 Human resources 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	There is a national drug policy implementation plan. If yes, enter the year of the document on newest in the field	Yes ☐ No ☒		

	"year "			
3.01.08	There is a clinical laboratory policy or group of policies. If yes, enter the year of the most recent document in the "year" field	Yes ☒ No ☐	2009	DNPL/MSHP
3.01.09	There is an implementation plan for the national clinical laboratory policy. If yes, enter the year of the most recent document in the "year" field	Yes ☐ No ☒		
3.01.10	Is access to essential technologies/medicines for the exercise of the right to health recognized in the national constitution or legislation ?	Yes ☒ No ☐	2009	Constitution national 2009
3.01.11	There are official written guidelines for donations of medications	Yes ☒ No ☐	1998	Instruction Ministerial No. 1707/MSP
3.01.12	Is the implementation of the pharmaceutical policy regularly monitored/evaluated ?	Yes ☐ No ☒		
3.01.12.01 Who is responsible for monitoring pharmaceutical policy?		It is the National Directorate of Pharmacy and Laboratory (DNPL)		
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 organizations are responsible?				
3.01.14	There is a policy to manage and sanction conflicts of interest in the pharmaceutical field	Yes ☒ No ☐	1994	L/012/CTRN (Art 22 and Art 101)
3.01.15	There is an official code of conduct for use by public officials	Yes ☐ No ☒		

3.01.16	Is there a mechanism for denunciation of abuses allowing individuals to alert the public to reprehensible acts committed in the pharmaceutical sector of your country (ombudsman) ?	Yes ☐ No ☒
3.01.16.01 Please describe the mechanism :		
3.01.17	Comments & references bibliographic	3.01.05: The following are considered political groups: the National Council of the Order of Pharmacists, the Union of Pharmacists and the National Medicines Commission. 3.01.06.06: A pharmacovigilance system has already been set up; It is in the experimental phase. 03.01.07: A draft PPN implementation plan is drawn up, it remains to be validated. 03.01.08: In application of the national medical biology policy document, a national medical biology commission has been set up 3.01.13: Guinea has just returned to democracy in 2010 following a transparent and democratic presidential election, with a view to good governance. 3.01.14: Law L94/012/CTRN is being revised.

Section 4 Trade and production of medicines

4.00 Registrant Information for Section 4

4.00.01	Name of person responsible for completing this section of the instrument	Ansoumane BERETE, Deputy National Trade Director Exterior, Ministry of Commerce
4.00.02	Phone number	(224) 30 43 10 48 / 64 40 79 98
4.00.03	E-mail address	ansoumaneb@yahoo.fr
4.00.04	Other registrants for this section Ousmane KABA and Aboubacar SYLLA, Property Department Industrial, Ministry of Industry.	

4.1 Intellectual Property Rights and Medicines Basic Questions

			Year	Source
4.01.01	The country is a member of the World Trade Organization Trade	Yes ☒ No ☐	1995	WTO
4.01.02	The law governs the granting of patents protecting :	Yes	1990	Agreement of bangui
4.01.02.01 Pharmaceutical products		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 indicate the Name and address of the institution responsible for the management and enforcement of intellectual property rights		Industrial Property Service (SPI), Ministry of Industry		
4.01.03.02 Please provide URL				

4.01.04	National legislation has been amended to implement the TRIPS Agreement	Yes ☒ No ☐	2001	Law L2001/007 from 06/11/2001
4.01.05	Current laws contain flexibilities and safeguards (TRIPS)	Yes ☒ No ☐		
4.01.06	The country fulfills the eligibility criteria for the transition period until 2016	Yes ☒ No ☐	2010	WTO
4.01.07	Which of the following flexibilities and safeguards (TRIPS) are present in the national legislation ?	Yes	2007	WHO Level 1
4.01.07.01 Compulsory license provisions that may be applied for public health reasons		Yes ☒ No ☐		
4.01.07.02 Bolar exception		Yes ☒ No ☐		
4.01.08	Does national legislation contain provisions on parallel imports ?	Yes ☒ No ☐		
4.01.09	The country has taken initiatives to strengthen its capacity to manage and enforce intellectual property rights and contribute to innovation and promote public health	Yes ☒ No ☐		
4.01.10	Does the law protect pharmaceutical product data exclusivity ?	Yes ☒ No ☐		
4.01.11	The law allows the extension of patents	Yes ☒ No ☐		
4.01.12	The law provides for the interdependence between patent status and marketing authorization	Yes ☒ No ☐		
4.01.13	Comments & references bibliographic	04.01.09: Guinea, as a member country of WIPO and OAPI, has requested and obtained various capacity building programs in the field of TRIPS from these organizations. Similarly, in 2006, AITIC provided a training program for Guinean executives in the same field. The Bangui Agreement which is the national law on intellectual property in the 16 states		

		members of the African Intellectual Property Organization (OAPI), of which the Republic of Guinea was revised on February 24, 1999 to take into account the provisions of the Agreement on Trade-Related Intellectual Property Rights (TRIPS), of which the integration of office licenses on patents. (cf revised Bangui Agreement of February 24, 1999, Annex 1 on patents of invention-article 56)		

4.02 Manufacturing

Basic Questions

			Year	Source
4.02.01	Number of licensed pharmaceutical manufacturers in the country	1	2007	DNPL
4.02.02	The country has manufacturing capabilities for :	Yes	2007	WHO Level 1
4.02.02.01 R&D to discover new active ingredients		Yes ☒ No ☐ Not known ☐		
4.02.02.02 Production of pharmaceutical raw materials (API)		Yes ☐ No ☒ Not known ☐		
4.02.02.03 The production of formulations from pharmaceutical raw materials		Yes ☒ No ☐ Not known ☐		
4.02.02.04 Repackaging of dosage forms		Yes ☒ No ☐ Not known ☐		
4.02.03	Percentage of market share in value produced by domestic manufacturers (%)			
4.02.04	Comments & references bibliographic	4.02.01: The only industrial unit holding a license for manufacture is called SODONGPHARMAGUI born from the rehabilitation of the national pharmaceutical company ENIPHARGUI with Chinese economic operators. 4.02.02.01: There is the Research and Valorization Center Medicinal Plants of Dubréka 4.02.02.03: Resource persons exist, but the Company (ENIPHARGUI) has been closed as part of		

		State withdrawal from the productive sector (structural adjustment).

Additional Questions

			Year	Source
4.02.05S	Percentage of market share by volume produced by domestic manufacturers (%)			
4.02.06S	Number of laboratories multinational pharmaceutical companies manufacturing drugs locally			
4.02.07S	Number of manufacturers having obtained the Good Manufacturing Practices (BFI) certificate			
4.02.08S	Comments & bibliographical references			

Section 5 Pharmaceutical regulations

5.00 Registrant Information for Section 5

5.00.01	Name of person responsible for completing this section of the instrument	Dr Harirata BAH, National Director of Pharmacy and Laboratory
5.00.02	Phone number	(224) 60 29 70 71
5.00.03	E-mail address	harirata@yahoo.fr
5.00.04	Other registrants for this section DR Binta BAH, Deputy DNPL	Dr Aboubacar Sidiki DIAKITE, IGS Dr Lamine DAFFE, Head of Medicines Division Dr Lansana Sandry CAMARA, in charge of narcotics and Psychotropic substances Dr Fatoumata Oury DIALLO, LNCQM

5.01 Regulatory Framework Basic Questions

			Year	Source
5.01.01	Does the law define the powers and responsibilities of the Pharmaceutical Regulatory Authority ?	Yes ☒ No ☐	1994	Law L94/012/CTRN Decree D94/043/PRG
5.01.02	There is an Authority of Pharmaceutical regulations	Yes ☒ No ☐	1992	Decree D92/PRG May 26, 1992
5.01.03	If yes, please indicate the Name and address of the Authority of Pharmaceutical regulations	National Directorate of Pharmacy and Laboratory BP:585 Tel: (224) 30 45 20 28		
5.01.04	Regulatory Authority			

	Pharmaceutical :	Yes ☒			
5.01.04.01 Part of Ministry of Health		Yes ☒			
5.01.04.02 Is a semi-autonomous organization		Yes ☐			
5.01.04.03 Other (specify)					
5.01.05	What are the functions of the national regulatory authority ?	Yes			
5.01.05.01	Placing authorization market/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	Drug advertising and promotion	Yes ☒	No ☐		
5.01.05.08	Clinical tests	Yes ☐	No ☒		
5.01.05.09	Pharmacovigilance	Yes ☒	No ☐		
5.01.05.10	Others (please explain)				
5.01.06	What is the permanent staff of the drug regulatory authority?	23		2011	DNPL
5.01.06.01 Please indicate the date of this reply		04/25/2011			
5.01.07	The drug regulatory authority has its own site website	Yes ☐	No ☒		
5.01.07.01 - If yes, please enter the drug regulatory authority website address (URL)					
5.01.08	The regulatory authority	Yes ☒	No ☐		

	pharmaceutical company benefits from external technical assistance			
5.01.08.01 If yes, please describe		The ARP sometimes benefits from occasional support from certain partners. This is the case of WHO, UNFPA and UNICEF		
5.01.09	The drug regulatory authority participates in harmonization/ collaboration	Yes ☒ No ☐	2007	WHO Level 1
5.01.09.01 - If yes, please specify Participation in regional workshops organized by WAHO.				
5.01.10	The drug regulatory system has been assessed over the past five years	Yes ☐ No ☒		
5.01.11	The drug regulatory authority receives funding from the regular state budget	Yes ☒ No ☐	2010	DNPL
5.01.12	The drug regulatory authority is funded by payment for services provided	Yes ☒ No ☐	2007	WHO Level 1
5.01.13	Drug regulatory authority receives funds/support from other sources	Yes ☒ No ☐		
5.01.13.01 - If yes, please specify Some partners support the programs implemented by DNPL: WHO, UNFPA, UNICEF				
5.01.14	Revenue from regulatory activities is retained by the regulator	Yes ☒ No ☐	2005	Stopped A/2005/5895/ MSP/MEF/S GG of 05/12/2005
5.01.15	The regulatory authority uses a computerized information management system to store and retrieve data relating to certification, inspections, etc.	Yes ☒ No ☐		
5.01.16	Comments & bibliographical references	5.01.05.02: Inspection is seconded to the General Health Inspectorate 5.01.11: The funds from the State's ordinary budget are essentially made up of salaries. 5.01.14: Fees collected for visas		

		drug registration fees are paid into the public treasury. However, the Joint Order of the Ministers of Health and that of Economy and Finance No. A/2005/5895 affects 50% of receipts to the DNPL for the purchase of inputs and reagents within the framework of the quality control of drugs.		

5.02 Marketing Authorization (Approval) Basic Questions

			Year	Source
5.02.01	A marketing authorization (registration) is mandatory for all pharmaceutical products marketed	Yes ☒ No ☐	1990	Stopped No. 3756/MSP P/CAB/90 of 06/09/90
5.02.02	Is there a mechanism exception/exemption from registration?	Yes ☒ No ☐	1994	Law L94/012/CTR N (Art 15)
5.02.03	There are mechanisms for recognition of registrations by other countries	Yes ☒ No ☐	1998	DNPL
5.02.03.01 If yes, please explain Provide registration application files accompanied by the list of countries where the molecules have already been registered and the related certificates. It is planned to set up a network of ARPs on the initiative of the LeM				
5.02.04	The assessment of marketing authorization applications for pharmaceutical products is based on well-defined public criteria	Yes ☒ No ☐	2000	Stopped No. 4901/MSP of 11/02/2000
5.02.05	Information provided by the WHO-run prequalification program is used for product registration	Yes ☒ No ☐	2007	
5.02.06	Number of pharmaceutical products registered in your country	2,233	2011	DNPL
5.02.07	The law defines the periodicity of the publication of the list of products	Yes ☒ No ☐	1995	DNPL

	licensed pharmaceuticals			
5.02.07.01 - If yes, frequency of updates		Every year		
5.02.07.02 - If yes, please enter updated list or URL				
5.02.08	Drug registration always contains the INN (international nonproprietary name)	Yes ☒ No ☐	1991	DNPL
5.02.09	The law provides for the payment of a fee for applications for authorization to market medicinal products (approval)	Yes ☒ No ☐	1991	DNPL
5.02.10	Comments & bibliographical references	5.02.02: Exceptions/exemption from registration are granted for Vaccines, supplies in the event of a call for tenders, etc; 05.02.09: The amount of the fee for registration applications was revised upwards by Joint Order Minister of Health and Minister of Economy and Finance in 2005: A/2005/5895 of 05/12/2005		

Additional Questions

			Year	Source
5.02.11S	Marketing authorization holders are required to provide information on changes to the existing authorization	Yes ☒ No ☐	1991	DNPL
5.02.12S	Publication of a Summary of Product Characteristics is mandatory for licensed medicinal products	Yes ☒ No ☐	1991	DNPL
5.02.13S	The law requires the creation of a committee of experts associated with the marketing authorization process	Yes ☒ No ☐	1994	Law L94/012/CTRN
5.02.14S	Any application for marketing authorization must be accompanied by a certificate of pharmaceutical product in accordance with the WHO certification system	Yes ☒ No ☐	2007	WHO Level 1
5.02.15S	The law requires a declaration of conflict of interest by experts	Yes ☐ No ☒		

	associated with registration assessment and decision-making			
5.02.16S	The law allows applicants to appeal decisions of the drug regulatory authority	Yes ☒ No ☐	1994	Law L94/012
5.02.17S	Registration fee – amount per application for pharmaceutical products containing a New chemical entity, NCE (US$)	135.95	2011	DNPL
5.02.18S	Registration fee – amount per request for a generic pharmaceutical product (US$)	135.95	2011	DNPL
5.02.19S	Deadline for the evaluation of a marketing authorization application (months)	6	1994	Law L/012
5.02.20S Comments & References bibliographic		05.02.13: A draft Order creating the Committee of Experts for the marketing authorization of medicinal products is drawn up, but has not yet been signed. 5.02.17S: The royalty rate is a fixed amount, fixed in Guinean francs. Its value in USD fluctuates according to the exchange rate of the day.		

5.03 Regulatory Inspection Basic Questions

			Year	Source
5.03.01	The law provides for the Appointment of public pharmaceutical inspectors	Yes ☒ No ☐	1994	Law L/012
5.03.02	The law authorizes inspectors to inspect the premises where pharmaceutical activities take place	Yes ☒ No ☐	1994	Law L/012
5.03.02.01	If yes, inspections are mandatory	Yes ☒ No ☐		
5.03.03	Inspection is a prerequisite for the issuance of a license for :	Yes		
5.03.03.01	Public establishments	Yes ☒ No ☐		

5.03.03.02 Private establishments		Yes ☒ No ☐		
5.03.04	Public establishments and private establishments are subject to the same inspection requirements	Yes ☒ No ☐	1994	Law L/012
5.03.05.01 Local laboratory inspections focus on compliance with good manufacturing practices		Yes ☒ No ☐	1994	Law L/012
5.03.05.02 Private wholesalers subject to inspections		Yes ☒ No ☐		
5.03.05.03 Retail pharmacies are inspected 5.03.05.04 Public pharmacies and warehouses are inspected		Yes ☒ No ☐		
		Yes ☒ No ☐		
5.03.05.05 Pharmacies and points of sale in health establishments are inspected		Yes ☒ No ☐		
5.03.05.06 Please provide details of the frequency of inspections of different categories of establishments		As a rule, each establishment must be inspected once a year; but for budgetary constraints in particular, this is not effective.		
5.03.06	Comments & bibliographical references	5.03.03.01: Law L94/012 provides in its Article N°62 that: "Any opening of a pharmacy within a hospital establishment, or a semi-public company must be the subject of a authorization granted by the Minister in charge of Health after consulting the Regional Pharmacist Inspector….." However, in practice, there is a tacit authorization for the opening of the pharmacy at the time of the creation of the public establishment.		

5.04 Import Control Basic Questions

			Year	Source
5.04.01	The importation of medicines is subject to authorization	Yes ☒ No ☐	1999	DNPL
5.04.02	The law provides for the taking of samples of imported products for examination purposes	Yes ☒ No ☐	1994	Law L/012
5.04.03	Importation of drugs is limited to authorized ports of entry	Yes ☒ No ☐		

5.04.04	The law provides for the inspection of imported pharmaceutical products at the authorized port of entry	Yes ☒ No ☐		
5.04.05	Comments & bibliographical references	5.04.03: This provision is not enforced 5.04.04: Provision not applied also		

5.05 Grant of Licenses
Basic Questions

			Year	Source
5.05.01	Manufacturers are required to hold a license.	Yes ☒ No ☐	1994	Law L/012
5.05.02	National and international manufacturers are required to comply with good manufacturing practices (GMP)	Yes ☒ No ☐	1994	Law L/012
5.05.02.01 ***If No,*** please describe				
5.05.03	GMPs are published by public authorities	Yes ☐ No ☒		
5.05.04	Importers are required to hold a license	Yes ☒ No ☐	1994	Law L/012
5.05.05	Wholesalers and distributors are required to be licensed	Yes ☒ No ☐	1994	Law L/012
5.05.06	Wholesalers and distributors are required to comply with the good manufacturing practices **Please complete the corresponding questions in SECTION 7 at the same time "PURCHASE and DISTRIBUTION"**	Yes ☒ No ☐	1994	Law L/012
5.05.07	Good national distribution practices are published by the public authorities	Yes ☐ No ☒		
5.05.08	Pharmacists are required to be licensed	Yes ☒ No ☐	1994	Law L/012
5.05.09	Private pharmacies are required to be licensed	Yes ☒ No ☐	1994	Law L/012
5.05.10	Public pharmacies are required to hold a license	Yes ☒ No ☐	1994	Law L/012

5.05.11	National good pharmaceutical practices are published by public authorities	Yes ☒ No ☐	1994	Law L/012
5.05.12	Publication of the list of licensed pharmaceutical establishments is mandatory	Yes ☐ No ☒		
5.05.13	Comments & references bibliographic	5.05.03: There is no national GMP document. However, professional ethics are essential in all circumstances. 5.05.10: This provision is provided for in Article 62 of Law L94/012, but it is not applied.		

5.06 Market Control and Quality Control Basic Questions

			Year	Source
5.06.01	The regulation of the pharmaceutical market is governed by law	Yes ☒ No ☐	1994	Law L/012
5.06.02	Is there a laboratory in the country that performs quality control testing?	Yes ☒ No ☐		
5.06.02.01 If yes, the laboratory	is it under the drug regulatory authority?	Yes ☒ No ☐		
5.06.02.02 Does the regulator secure services	elsewhere ? by contract ?	Yes ☒ No ☐		
5.06.02.03 If yes, please describe		The DNPL sometimes cooperates with the Center Humanitaire Médico Pharmaceutique (CHMP) in Clermont Ferand (in France) under the guise of the LeM for the quality control of certain products. This is free assistance.		
5.06.03	Is a national laboratory authorized to collaborate with the WHO prequalification programme? Explain	Yes! As a member country of the Organization.		
5.06.04	Medications are controlled:	Yes		
5.06.04.01 To ensure their quality in the public	sector (deduction	Yes ☒ No ☐		

	systematic sampling in pharmaceutical warehouses and health facilities)			
5.06.04.02 To ensure their quality in the private sector (systematic taking of samples from retailers)		Yes ☒ No ☐		
5.06.04.03 In the event of a complaint or when a problem is reported		Yes ☒ No ☐		
5.06.04.04 For product certification		Yes ☒ No ☐		
5.06.04.05 For pre-selection for public procurement		Yes ☒ No ☐		
5.06.04.06 For products intended for public programs prior to acceptance and/or distribution		Yes ☐ No ☒		
5.06.05	Samples are collected by government inspectors for post-marketing controls	Yes ☒ No ☐	1994	Law L/012
5.06.06	How many samples have been collected over the past two years for quality control purposes ?	86	2010	LNCQM
5.06.07	Total number of samples checked in the last two years that did not meet the quality criteria	19	2010	LNCQM
5.06.08	The results of the controls of quality of the last two years have been published	Yes ☒ No ☐	2010	LNCQM
5.06.09	Comments & references bibliographic	05.06.04.01: An Order of the Minister of Health makes quality control of medicines mandatory at all stages of supply, but its application is not systematic 5.06.08: Control results would be forwarded to DNPL by the LNCQM.		

5.07 Drug advertising and drug promotion Basic questions

		Year	Source

5.07.01	Promotion and/or advertising of prescription drugs is regulated Who is responsible for regulating the promotion and/or advertising	Yes ☒ No ☐	1994	Law L/012
5.07.02	of drugs?	DNPL/MSHP		
5.07.03	Law bans direct-to-public advertising of prescription drugs	Yes ☒ No ☐	1994	Law L/012 (Art. 31)
5.07.04	Advertising and promotional materials for medicines must obtain a prior approval	Yes ☒ No ☐	1994	Decree D94/043/PRG (Art.R19)
5.07.05	There are guidelines/ regulations for the advertising and promotion of non-prescription drugs	Yes ☐ No ☒		
5.07.06	A national code of conduct on the advertising and promotion of medicinal products by marketing authorization holders has been published	Yes ☐ No ☒		
5.07.06.01 If so, the Code of Conduct applies:		Yes		
	Nationals only	Yes ☐		
	Multinationals only	Yes ☐		
	To each other	Yes ☐		
5.07.06.02 If yes, application of the code is voluntary		Yes ☐ No ☐		
5.07.06.03 If so, the code contains a formal process for complaints and sanctions		Yes ☐ No ☐		
5.07.06.04 If so, the list of complaints and sanctions for the last two years has been published		Yes ☐ No ☐		

5.07.07	Comments & references bibliographic	5.07.04: Pre-approval of advertising and promotional materials for drugs is not effective.

5.08 Clinical Trials Basic Questions

			Year	Source
5.08.01	The conduct of clinical trials must be authorized by the drug regulatory authority	Yes ☒ No ☐		
5.08.02	Conducting clinical trials requires approval from an ethics committee/ institutional review board	Yes ☒ No ☐		
5.08.03	Registration of clinical trials in the international/national/ regional registry is mandatory	Yes ☒ No ☐		
5.08.04	Comments & references bibliographic	5.08.01: DNPL is a member of the Ethics Committee.		

Additional Questions

			Year	Source
5.08.05S	Products reviewed must be GMP compliant	Yes ☒ No ☐		
5.08.06S	The sponsor, the researcher must comply with good clinical practices (GCP)	Yes ☒ No ☐		
5.08.07S	National PCB regulations are published by the government	Yes ☒ No ☐		
5.08.08S	The law authorizes the inspection of establishments where clinical trials are carried out	Yes ☒ No ☐		
5.08.09S	Comments & bibliographical references			

5.09 Restricted Drugs Basic Questions

			Year	Source
5.09.01	The country has signed the conventions			

	following:	☒ Yes		
5.09.01.01	The Single Convention on Narcotic Drugs, 1961	Yes ☒ ☐	1968	International Narcotics control-board
5.09.01.02	The 1972 Protocol Amending the Single Convention on Narcotic Drugs, 1961	Yes ☒ ☐	1990	International Narcotics control-board
5.09.01.03	The 1971 Convention on psychotropic substances	Yes ☒ ☐	1990	International Narcotics control-board
5.09.01.04	The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	Yes ☒ ☐	1990	International Narcotics control-board
5.09.02	The law provides for the control of narcotics and psychotropic substances, and precursors	Yes ☒ ☐	1994	Law L/012 (Art 8)
5.09.03	Annual morphine consumption (mg/inhabitant)			
5.09.04	Comments & bibliographical references	5.09.03: No request for morphine was recorded at the level of the DNPL during the year.		

Additional Questions

			Year	Source
5.09.05S	An international expert or WHO partner organization has reviewed the legal provisions and regulations applicable to the control of narcotic drugs and psychotropic substances, and precursors to find the right balance between drug prevention and access for medical purposes	Yes ☒ ☐ Not known ☐		
5.09.05.01S	If yes, year of exam			
5.09.06S	Annual fentanyl consumption (mg/capita)	0.001004	2010	DNPL
5.09.07S	Annual pethidine consumption (mg/capita)			

5.09.08S	Annual consumption of oxycodone (mg/capita)			
5.09.09S	Annual consumption hydrocodone (mg/capita)			
5.09.10S	Annual consumption of phenobarbital (mg/capita)	1.364596	2010	DNPL
5.09.11S	Annual consumption of methadone (mg/capita)			
5.09.12S	Comments & bibliographical references	Other products are not on the national list of annual forecasts		

5.10 Pharmacovigilance Basic issues

			Year	Source
5.10.01	The mandate of the authority of pharmaceutical regulation includes activities of pharmacovigilance	Yes ☒ No ☐		
5.10.02	The holder of a marketing authorization is required to continuously monitor the safety of its products and report to the drug regulatory authority	Yes ☐ No ☒		
5.10.03	Monitoring for adverse drug reactions is mandatory in your country	Yes ☐ No ☒		
5.10.04	Your country has a national pharmacovigilance center	Yes ☐ No ☒		
5.10.04.01	If yes, what is full-time workforce?			
5.10.04.02	If yes, an analysis report has been published within the last two years	Yes ☒ No ☐		
5.10.04.03	If so, the center publishes an adverse drug reaction newsletter	Yes ☒ No ☐		
5.10.05	An official standardized form of adverse reaction reporting	Yes ☒ No ☐	2008	DNPL

	medication is used in your country			
5.10.06	Your country has a national effects database adverse drug reactions	Yes ☒ No ☐	2010	DNPL
5.10.07	How much the database Does it contain any reports of adverse effects of drugs ?	40	2010	DNPL
5.10.08	How many reports have been received in the past two years ?	40	2010	DNPL
5.10.09	Adverse drug reaction reports are they sent to the WHO database in Uppsala ?	Yes ☒ No ☐	2010	DNPL
5.10.09.01 If yes, Number of reports sent in the past two years				
5.10.10	Is there a Pharmacovigilance Advisory Committee able to provide technical assistance on causality assessment, risk assessment, case investigation and, if necessary, crisis management, including crisis communication?	Yes ☐ No ☒		
5.10.11	Is there a communication strategy for regular communication and crisis communication?	Yes ☐ No ☒		
5.10.12	In the absence of a national pharmacovigilance system, adverse drug reactions are monitored in at least one public health program (e.g. tuberculosis, HIV, AIDS)	Yes ☒ No ☐		
5.10.13	Please describe here how you intend to improve the pharmacovigilance system	At the national level, some measures are taken within the framework of pharmacovigilance, namely: 1- Raising stakeholders' awareness of the importance of pharmacovigilance 2- Development of data collection sheets: these sheets are		

		validated, tested and edited 3- The staff is trained in filling wastelands 4- Provision of the sheets in order to make their use effective. 5. Follow-up of cases of side effects with report during the mass vaccination campaign (Vaccination against Yellow Fever.. Prospects: Create a National Center for Pharmacovigilance and set up Pharmacovigilance Committees in each of the health facilities and have Guinea adhere to the world pharmacovigilance organization.
5.10.14	Comments & bibliographical references	5.10.12: Each program tracks the molecules it uses.

Additional Questions

			Year	Source
5.10.15S	Information is communicated back to the authors of the reports	Yes No ☒		
5.10.16S	The adverse drug reaction database is computerized	Yes No ☒		
5.10.17S	Medication errors are reported	Yes No ☒		
5.10.18S	How many medication errors listed in the Adverse Reaction Database for drugs ?			
5.10.19S	Product dossiers accompanying marketing authorization applications contain a risk management plan?	Yes ☐ No ☒		
5.10.20S	Who in the past two years has reported adverse drug reactions ?	Yes		
5.10.20.01S	Doctors	☒ Yes		

5.10.20.02S	Nursing staff	☐ Yes		
5.10.20.03S	Pharmacists	☐ Yes		
5.10.20.04S	patients	☐ Yes		
5.10.20.05S	Pharmaceutical laboratories	☒ Yes		
5.10.20.06S	Other, please specify	WHO, AFSSAPS		
5.10.21S	Was a regulatory decision made based on local data relating to the pharmacovigilance over the past two years ?	Yes ☐ No ☒		
5.10.22S	Are there any training courses pharmacovigilance ?	Yes ☐ No ☒		
5.10.22.01S	If so, how many people have been trained in the past two years ?			
5.10.23S	Comments & References bibliographic	5.10.22S: The staff training that took place focused on completing the data collection sheets.		

Section 6 Drug financing

6.00 Registrant Information for Section 6

6.00.01	Name of person responsible for completing this section of the instrument	Dr Harirata BAH
6.00.02	Phone number	(224) 60 29 70 71
6.00.03	E-mail address	harirata@yahoo.fr
6.00.04	Other registrants for this section	Dr Ismael DIALLO, Physician, Sickness Department at UGAR Dr Jean MARA, Physician, Deputy Medical Advisor to the CNSS

6.01 Drug Benefits and Exemptions Basic Questions

			Year	Source
6.01.01	Are the drugs free for :	Yes		
6.01.01.01	Patients who cannot afford them	Yes ☒ No ☐		
6.01.01.02	Children under five	Yes ☒ No ☐		
6.01.01.03	Pregnant women	Yes ☒ No ☐		
6.01.01.04	The elderly	Yes ☐ No ☒		
6.01.01.05	If yes, please describe/explain	6.01.01.02 and 6.01.01.03: The country's new health policy stipulates that all care for pregnant women and children under five is free.		
6.01.02	Are drugs provided free of charge under a public health system or social security program for:	Yes		

6.01.02.01 All drugs included in the list of essential medicines	Yes ☒	No ☒
6.01.02.02 All diseases transmissible	Yes ☒	No ☒
6.01.02.03 Antimalarials	Yes ☒	No ☐
6.01.02.04 Antituberculosis drugs	Yes ☒	No ☐
6.01.02.05 Medicines for sexually transmitted diseases	Yes ☒	No ☒
6.01.02.06 Medicines for HIV/AIDS	Yes ☒	No ☐
6.01.02.07 EPI vaccines	Yes ☒	No ☐
6.01.02.08 Other, please specify	Cesarean kit, Antileprosy, Ivermectin, Vitamin A and mebendazole for children	
6.01.02.09 If yes, please describe/explain	6.01.02.06: It is defined at the level of the Ministry of Health of patient program eligibility criteria. Only patients admitted to the program are supported for the dispensation of ARVs.	
6.01.03 Are medicines covered, at least partially, by health insurance? national, social security system or other health fund ?	Yes ☒	No ☐
6.01.03.01 Medications in the list of are essential drugs covered for **hospitalized** patients ?	Yes ☒	No ☐
6.01.03.02 Medications in the list of are essential drugs covered for **outpatients ?**	Yes ☒	No ☐
6.01.03.03 Please describe the pharmaceutical benefits of public insurance schemes	Pharmaceutical services are provided by community pharmacists contracted with the insurance structures.	
6.01.04 Do private health insurance schemes pay for	Yes ☒	No ☐

	drugs ?	
6.01.04.01	If yes, are they required to pay for drugs included in the list of drugs essential?	Yes ☒ No ☐
6.01.05	Comments & references bibliographic	6.01.01.01: There is an indigence fund in the form of a State subsidy in public health facilities. 6.01.02.03: This free treatment relates to therapeutic combinations based on arthemesinine and sulphadoxi pyrimethamine. In general, the reimbursements do not specifically take into account the fact that the molecules are on the national list of essential drugs. The reimbursement rates vary according to the insurance plans (from 70 to 100%).

6.02 Payment by patients and co-payments Basic questions

			Year	Source
6.02.01	Does your health system provide for patient payment/co-payment for consultations?	Yes ☒ No ☐	1988	MSHP
6.02.02	Does your health system provide for patient payment/co-payment for medicines?	Yes ☒ No ☐	1988	MSHP
6.02.03	*In practice, (even if it may be illegal)* are the proceeds from the payment or sale of drugs *sometimes* used to pay the salaries or supplement the income of public health personnel in the same establishment?	Yes ☒ No ☐	1988	MSHP
6.02.03.01	Please describe the patient payment and co-payment system	Payments are made by package or in split rates depending on the level of the health structure. For Health Centers and Health Posts, the package includes consultation and medication. There is also price discrimination between children and		

		adult.		
6.02.04	Comments & bibliographical references	6.02.03: Cost recovery has been instituted for primary health care since 1988. The revenues are used to guarantee the functioning of the health structure. It provides for the payment of performance bonuses to staff.		

6.03 Price regulation for the private sector Basic questions

			Year	Source
6.03.01	Do legal or regulatory provisions influence drug prices?	Yes ☒ No ☐	1985	Stopped spouse No. 8486/MC/MSP/ of 09/09/1985 fixing the structure of prices of pharmaceutical products and sp ues.
6.03.01.01	If yes, do these provisions apply to manufacturers ?	Yes ☐ No ☒		
6.03.01.02	If so, do these provisions apply to wholesalers ?	Yes ☒ No ☐		
6.03.01.03	If yes, do these provisions apply to retailers ?	Yes ☒ No ☐		
6.03.01.04	If yes, please explain: (explain the scope of the provisions: generics as opposed to pharmaceutical specialties or subsets of medicines, list of essential medicines, etc.)	This provision made no mention of generics. On the other hand, later provisions made the case of social medicines (medicines for preventive use and medicines intended for the treatment of chronic and/or disabling diseases). Margins have been reduced for these drugs.		
6.03.02	The government has established an effective national system for monitoring retail drug prices	Yes ☐ No ☒	2007	WHO level 1
6.03.03	Current regulations require the publication of retail drug prices	Yes ☒ No ☐	2007	WHO level 1

6.03.03.01 - If yes, please explain how this information is published		Each wholesaler-distributor Company publishes its sale prices and its public prices for its customers. But the pharmaceutical administration does not publish a national pharmaceutical tariff.
6.03.04	Comments & bibliographical references	6.03.01.01: Manufacturers register drugs with their wholesale prices excluding taxes

6.04 Pricing, Availability and Affordability Basic Questions

			Year	Source
	Please indicate if a medicine price survey using the WHO/HAI method has been carried out in your country in the last five years	Yes ☐ No ☒ Not known ☐ ***If yes,*** please indicate the year of the survey and use the results to populate this table ***If No,*** but other medicine prices and availability surveys have been done, do not use them to complete this section, but use the comments field to provide some of the results and attach the report to the questionnaire		

Basket of main drugs			**Public purchases**	**Public patients**	**Private patients**
Availability (either or both)	Medium (%)	**Origin**	[redacted]	6.04.01.01	6.04.01.03
		cheapest generic		6.04.01.02	6.04.01.04
	Median (%)	**Origin**		6.04.02.01	6.04.02.03

		cheapest generic		6.04.02.02	6.04.02.04
Price	Median price ratio	**Origin**	6.04.03.01	6.04.03.03	6.04.03.05
		cheapest generic	6.04.03.02	6.04.03.04	6.04.03.06
Accessibility financial Days of salary of the lowest paid civil servant for the standard treatment with cotrimoxazole of a respiratory infection in a child	Number of salary days	**Origin**		6.04.04.01	6.04.04.03
		cheapest generic		6.04.04.02	6.04.04.04

6.04.05	Comments & references bibliographic	

6.05 Price Components and Affordability Basic Questions

			Year	Source
6.05.01	Please indicate if a survey on the components of medicine prices has been carried out in your country in the past five years. If yes, please indicate the year of the survey and use the results to inform the questions below Average cumulative markup percentage between the MSP/CIF price and the final price of a medicine for a basket of main medicines	Yes ☒ No Not known ☐		
6.05.02	in the public sector (% average contribution)			
6.05.03	Average cumulative margin percentage between the MSP/CIF price and the final price of a medicine for a basket of main medicines			

	in the private sector (% average contribution)	
6.05.04	Comments & bibliographical references	
Additional Questions		
6.05.05S	Average percentage of MSP/CIF contribution to the final drug price for a basket of main drugs in the public sector (% of average contribution)	
6.05.06S	Average percentage of MSP/CIF contribution to the final drug price for a basket of main drugs in the private sector (% of average contribution)	
6.05.07S	Manufacturer's Average Selling Price (CIF) as a percentage of the final drug price for a basket of core drugs (%)	
6.05.08S	Average wholesaler selling price as a percentage of final drug price for a core drug basket (%)	
6.05.09S	Pharmacist's average margin or fees on procedures medicines as a percentage of the retail price for a basket of main medicines (%)	
6.05.10S	Average percentage contribution of the wholesaler's margin to the final drug price for a basket of main drugs (in the public and private sectors) (%)	
6.05.11S	Average percentage contribution of the retailer's margin to the final medicine price for a basket of main medicines (in the public and private sectors) (%)	

6.05.12S Comments & References bibliographic		

6.06 Duties and taxes on pharmaceutical products (market)
Basic Questions

			Year	Source
6.06.01	Duties are levied on imported pharmaceutical active ingredients (Apis)	Yes ☒ No ☐	1990	Decree No.
6.06.02	Duties are levied on imported finished products	Yes ☒ No ☐	1990	
6.06.03	A VAT (Value Added Tax) or other tax is levied on finished pharmaceutical products	Yes ☒ No ☐	2005	Stopped No. 00126/MEF /CAB of 01/31/2005
6.06.04	The law provides exceptions for pharmaceutical and health products	Yes ☒ No ☐	2004	Stopped No. 7058/MCIP ME/SGG/ of 07/01/2004
6.06.05	Please specify on which categories of pharmaceutical products the taxes are levied and describe the exemptions and waivers that exist	Medical devices and consumables are taxed as well as raw materials and packaging items (about 43% on consumables).		
6.06.06	Comments & bibliographical references			

Additional Questions

			Year	Source
6.06.07S	Amount of duties on imported pharmaceutical assets, APIs (%)			
6.06.08S	Amount of duties on imported finished products (%)			
6.06.09S	Amount of VAT on finished pharmaceutical products (%)			
6.06.10S Comments & bibliographical references				

Section 7 Purchasing and Distribution of Pharmaceuticals

7.00 Registrant Information for Section 7

7.00.01	Name of person responsible for completing this section of the instrument	Dr Awa TOURE
7.00.02	Phone number	60 21 38 94
7.00.03	E-mail address	
7.00.04	Other registrants for this section	Dr Abdoulaye Tangaly DIALLO

7.01 Public Sector Procurement
Basic Questions

			Year	Source
7.01.01	Public sector purchases are	Yes		
7.01.01.01 Decentralized		☐ Yes		
7.01.01.02 Centralized and decentralized		☒ Yes		
7.01.01.03 Please describe		The public sector is supplied by both the Pharmacy Centrale de Guinée (PCG) and partners who support specific health programs		
7.01.02	If public sector procurement is fully or partially centralised, it falls under a procurement body which :	Yes		
7.01.02.01 Part of Ministry of Health Yes No		☒ ☐		
7.01.02.02 Is semi-autonomous		Yes ☒ No ☐		
7.01.02.03 Is autonomous		Yes ☒ No ☐		
7.01.02.04 Is a public purchasing organization		Yes ☒ No ☐		

	who buys all the public goods			
7.01.03	Public sector tender documents are published	Yes ☒ No ☐	2006	PCG
7.01.04	Public sector concessions are published	Yes ☒ No ☐	2006	PCG
7.01.05	Purchasing is based on a pre-selection of suppliers	Yes ☒ No ☐	2006	PCG
7.01.05.01 Please describe the terms		Calls for pre-selection of suppliers are made every 2 years. The reports are available in the PCG archives		
7.01.06	Comments & bibliographical references			

Additional Questions

			Year	Source
7.01.07S	Is there a written public sector procurement policy? If yes, please enter the year of approval in the "year" field	Yes ☒ No ☐	2006	Manual of PCG procedures
7.01.08S	Does the law give priority to public purchases of goods produced by local manufacturers ?	Yes ☐ No ☒		
7.01.09S	Are the main functions of the central purchasing office well distinct from those of the committee that examines the submissions	Yes ☒ No ☐	2006	PCG
7.01.10S	There is a quality assurance process for purchased products	Yes ☒ No ☐	2006	PCG/ procedure manual
7.01.10.01 S	If so, the quality assurance process includes prequalification of products and suppliers	Yes ☒ No ☐		
7.01.10.02 S	If so, the prequalification of suppliers is based on well-defined criteria and procedures	Yes ☒ No ☐		
7.01.10.03 S	If yes, a list of prequalified suppliers and products is published	Yes ☒ No ☐		

7.01.11S	The list of samples checked during the purchase process and the results of the quality checks quality are available	Yes ☒ No ☐		
7.01.12S	Which of the following submission methods is used for public sector purchases:	Yes		
7.01.12.01 S	National tenders	Yes ☒ No ☐		
7.01.12.02 S	International tenders	Yes ☒ No ☐		
7.01.12.03 S	Direct purchases	Yes ☒ No ☐		
7.01.13S	Comments & References bibliographic	7.01.12S: Methods of submission obey the volume of purchase orders and product specifications		

7.02 Distribution in the public sector Main indicators

			Year	Source
7.02.01	The public supply system department has a national central medical warehouse	Yes ☒ No ☐	1992	PCG
7.02.02	Number of public warehouses at the secondary level of public distribution (national/regional/ provincial)	5	1992	PCG
7.02.03	There are national guidelines for Good Distribution Practices (GDP)	Yes ☒ No ☐	2006	PCG/Manual of procedure
7.02.04	An authority issues licenses for compliance with good distribution practices	Yes ☐ No ☒		
7.02.04.01	If yes, does it accredit public distribution establishments ?	Yes ☐ No ☐ Not known ☐		
7.02.05	There is a list of warehouses certified in accordance with the	Yes ☐ No ☐		

	good distribution practices in the public sector			
7.02.06	There is a list of distributors certified in accordance with the good distribution practices in the public sector	Yes ☒ No ☐		
7.02.07	Comments & bibliographical references			

Additional Questions

			Year	Source
7.02.08S	Which of the following processes is applied in the central medical warehouse :	Yes		
7.02.08.01S	Forecast of quantities to order	Yes ☒ No ☐		
7.02.08.02S	Stock release orders	Yes ☒ No ☐		
7.02.08.03S	Establishment of slips collection/packaging	Yes ☒ No ☐		
7.02.08.04S	On-hand inventory reports	Yes ☒ No ☐		
7.02.08.05S	Pending Orders Reports	Yes ☒ No ☐		
7.02.08.06S	Management of expiry dates Yes No	☒ ☐		
7.02.08.07S	Batch tracking	Yes ☒ No ☐		
7.02.08.08S	Out of Stock Product Reports	Yes ☒ No ☐		
7.02.09S	% availability of essential drugs			
7.02.10S	Average duration of stockouts for a basket of medicines in days			
7.02.11S	There is a method systematic control of	Yes ☒ No ☐	2006	PCG

	drug expiration dates			
7.02.12S	The public central medical warehouse is certified in accordance with the good distribution practices by the licensing authority	Yes ☒ No ☒		
7.02.13S	The public central medical warehouse is ISO certified	Yes ☒ No ☒		
7.02.14S	Tier 2 public warehouses are certified in compliance with good distribution practices by a licensing authority	Yes ☒ No ☒		
7.02.15S	Tier 2 public warehouses are also certified ISO	Yes ☒ No ☒		
7.02.16S Comments & References bibliographic		7.02.09S: PCG does not routinely order all drugs on the National Essential Drugs List; but according to customer needs. The PCG infrastructures have been designed taking into account the criteria of good distribution practice. However, no special certificate of GDP compliance has ever been issued for any of its facilities.		

7.03 Distribution in the private sector
Basic questions

			Year	Source
7.03.01	The law provides for the licensing of private sector wholesalers	Yes ☒ No ☐	1994	Law L/012
7.03.02	The law provides for the licensing of private sector distributors	Yes ☒ No ☐	1994	Law L/012
7.03.03	There is a list of wholesalers certified in accordance with the good distribution practices in the private sector	Yes ☒ No ☐	2011	DNPL
7.03.04	There is a list of distributors certified in accordance with the good distribution practices in the private sector	Yes ☒ No ☐	2011	DNPL

7.03.05	Comments & references bibliographic	The Wholesalers are at the same time the Distributors.

Section 8 Selection and Rational Use

8.00 Registrant Information for Section 8

8.00.01	Name of person responsible for completing this section of the instrument	Dr Fatoumata Kolon DIALLO, Head of Medicines Registration Section at DNPL
8.00.02	Phone number	(224) 64 58 89 56
8.00.03	E-mail address	
8.00.04	Other registrants for this section	Dr. Lansana Sandry CAMARA, DNPL

8.01 National Structures
Basic Questions

			Year	Source
8.01.01	There is a National Essential Medicines List (EML). If yes, please enter the year of the last EML update in the "year" field	Yes ☒ No ☐	2006	Stopped #2778 /MSP/CAB
8.01.01.01	If yes, Number of medicines in the EML (Number of INNs)	202		
8.01.01.02	If yes, a document describes how to select drugs included in the EML	Yes ☐ No ☒		
8.01.01.03	If yes, MEL is published	Yes ☐ No ☒		
8.01.01.04	If yes, is there a mechanism to align the EML with the Standardized Therapeutic Guidelines (GTN)	Yes ☒ No ☐		
8.01.02	The national Standardized Therapeutic Guides (GTN) for	Yes ☒ No ☐		

	common diseases are produced/approved by the Ministry of Health. In If yes, please enter the year of the last GTN update in the "year" field			
8.01.03	There are NWGs that apply specifically to primary health care. Please enter in the “year” field the year of the last update of the GTNs for primary health care There are GTNs that apply specifically to care	Yes ☒ No ☐	1988	MSP
8.01.04	at the secondary level (hospitals). Please enter in the "year" field the year of the last update of the GTN for care at secondary level	Yes ☒ No ☐	2005	MSP/DNPL
8.01.05	There are GTNs that apply specifically to pediatric conditions. Please enter in the "year" field the year of the last update of the GTNs for pediatric conditions	Yes ☒ No ☐	2008	Ministry of health
8.01.06 % (mean) of public health facilities with a copy of the EML – survey data 8.01.07 % (mean) of public health facilities with copies of the GTNs –				
survey data		66.5	2002	WHO rational use database
8.01.08	A public or independently funded national drug information center provides drug information to prescribers, community pharmacists and consumers	Yes ☒ No ☐		
8.01.09	Public education campaigns on the rational use of medicines have been organized over the past two years	Yes ☒ No ☐		

8.01.10	A survey on the rational use of medicines has been organized over the past two years	Yes ☐ No ☒		
8.01.11	A national program or committee (associating public authorities, civil society and professional organizations) is responsible for monitoring and promoting the rational use of medicines	Yes ☐ No ☒		
8.01.12	There is a written national resistance strategy to antimicrobials. If yes, please enter the year of the last strategy update in the "year" field	Yes ☐ No ☒		
8.01.13	Comments & bibliographical references	8.01.01.02: WHO guidelines are used occasionally as well as the experiences of prescribers and program managers. 8.01.05: In the PCIMNE and PNLP programs there is a national therapeutic guide relating to pediatric conditions.		

Additional Questions

			Year	Source
8.01.14S	LME includes pediatric formulations	Yes ☒ No ☐	200	DNPL
8.01.15S	Drug selection included in the EML is based on precise criteria, solidly substantiated	Yes ☒ No ☐	200	DNPL
8.01.16S	The selection of products on the national EML is the responsibility of an official committee or other equivalent structure	Yes ☐ No ☒		
8.01.16.01S	If so, a declaration of conflict of interest is required from members of the LME committee national	Yes ☐ No ☐		
8.01.17S	There are national drug formularies	Yes ☒ No ☐	1992	MSP
8.01.18S	A national intersectoral group special funding to coordinate the promotion of	Yes ☐ No ☒	2007	WHO level 1

	the appropriate use of antimicrobials and the prevention of the spread of infections ?			
8.01.19S A reference laboratory/a	another national body is responsible for coordinating epidemiological surveillance of antimicrobial resistance	Yes ☒ No ☐	2007	WHO level 1
8.01.20S Comments & bibliographical references		8.01.16S: For the selection of essential drugs, an ad hoc multidisciplinary commission is formed to develop a project which is validated during a workshop		

8.02 Limitation Basic Questions

			Year	Source
8.02.01	The granting of licenses to prescribers and prescribing practices are regulated by law	Yes ☒ No ☐	1994	Law L/012
8.02.02	The law limits the dispensing of drugs by prescribers Do private sector	Yes ☒ No ☐	1994	Law L/012
8.02.03	prescribers dispense drugs?	Yes ☒ No ☐		
8.02.04	Hospitals are required to organise/create Drug and Therapeutics Committees (DTCs)	Yes ☒ No ☐	2007	WHO level 1
8.02.05	Do more than half of referral hospitals have a CPT?	Yes ☒ No ☐ Not known ☐	2007	WHO level 1
8.02.06	Do more than half of general hospitals have a CPT?	Yes ☒ No ☐ Not known ☐	2007	WHO level 1
8.02.07	More than half of do regions/provinces have a CPT?	Yes ☒ No ☐ Not known ☐	2007	WHO level 1
8.02.08	The basic medical education program contains elements on :	Yes	2007	WHO level 1
8.02.08.01 The concept of LME		Yes ☒ No ☐		

8.02.08.02 The use of GTNs		Yes ☒ No ☐		
8.02.08.03 Pharmacovigilance		Yes ☐ No ☒		
8.02.08.04 Problem-based pharmacotherapy		Yes ☐ No ☒		
8.02.09	Physicians are required to follow continuing education including pharmaceutical questions	Yes ☒ No ☐		[2]
8.02.10	Nursing staff are required to undergo continuous training including pharmaceutical questions	Yes ☐ No ☒		
8.02.11	Paramedical staff are required to undergo continuous training including pharmaceutical matters	Yes ☐ No ☒	2007	WHO level 1
8.02.12	The use of INNs for prescriptions is mandatory in :	Yes	2007	WHO level 1
8.02.12.01 The public sector		Yes ☒ No ☐		
8.02.12.02 The private sector		Yes ☐ No ☒		
8.02.13	Average number of drugs prescribed per consultation in public health facilities (average) 8.02.14 % of drugs listed in the national EML prescribed on an outpatient			
basis in public	health care facilities (average)			
8.02.15 % of drugs prescribed by	outpatient ICDs in healthcare facilities public (medium)			
8.02.16 % of patients receiving antibiotics on	an outpatient basis in public health care facilities (average)	59.7	2002	WHO rational use database
8.02.17 % of patients receiving				

	outpatient injections in public health care facilities (average) 8.02.18 % of prescribed drugs dispensed to patients (average)			
8.02.19 % of drugs	appropriately labeled in health facilities public (medium)			
8.02.20	Comments & bibliographical references	8.02.12.01: National pharmaceutical regulations make INN prescription mandatory in the public sector (Article R22 of Decree D94/043/PRG of March 22, 1994) 8.02.13: No prescribing survey has been reported for the past 5 years.		

Additional Questions

			Year	Source
8.02.21S	The professional behavior of physicians is governed by a professional association code of conduct	Yes ☒ No ☐		
8.02.22S	The professional behavior of nurses is governed by an association code of conduct professional	Yes ☒ No ☐		
8.02.23S	Treatment of diarrhea in children relies on ORS (%)			
8.02.24S Comments		There have been no prescribing surveys for the past 5 years.		

8.03 Dispensing of drugs Basic questions

			year	Source
8.03.01	The dispensing of drugs by pharmaceutical staff is regulated by law	Yes ☒ No ☐	1994	L012
8.03.02	The basic training program for pharmacists includes elements relating to	Yes	2007	WHO level 1

following points :				
8.03.02.01 The concept of LME		Yes ☒ No ☐		
8.03.02.02 The use of GTNs		Yes ☒ No ☐		
8.03.02.03 Pharmaceutical information Yes No		☒ ☐		
8.03.02.04 Clinical pharmacology		Yes ☒ No ☐		
8.03.02.05 Supply management in drugs		Yes ☒ No ☐		
8.03.03	Pharmacists are required to undergo continuing education including the rational use of medicines	Yes ☐ No ☒		
8.03.04	The law authorizes substitution by generic equivalents at the point of dispensing in public sector establishments	Yes ☒ No ☐	1994	Decree 94/043(Art. R23
8.03.05	The law authorizes substitution by generic equivalents at the place of issue in private sector facilities *In practice,*	Yes ☒ No ☐	2007	WHO level 1
8.03.06	*(although this may be prohibited) are* antibiotics ever sold over the counter without a prescription?	Yes ☒ No ☐ Not known ☐	2007	WHO level 1
8.03.07	*In practice (although this may be prohibited) are* injections ever sold over the counter without a prescription?	Yes ☒ No ☐ Not known ☐	2007	WHO level 1
8.03.08	Comments & bibliographical references	8.03.04: Although the law authorizes the substitution of pharmaceutical specialties by their generic equivalents, we note on the ground, some resistance on the part of prescribers to accept it.		
Additional Questions				
			Year	Source
8.03.09S	The professional behavior of pharmacists is governed by a code of conduct of the association professional	Yes ☒ No ☐	1994	Law L/012 and Decree D/043 from March 22

				1994
8.03.10S *In practice, (although this may be prohibited)* do the following other categories of personnel ever prescribe prescription-only medicines at the first level of care in the public sector?		Yes	2007	WHO level 1
8.03.10.01S	Nursing staff	Yes ☒ No Not known ☐		
8.03.10.02S	Pharmacists	Yes ☐ No Not known ☒		
8.03.10.03S	Paramedical personnel	Yes ☒ No Not known ☐		
8.03.10.04S	Staff with less than one month of training	Yes ☐ No Not known ☒		
8.03.11S Comments & References bibliographic		8.03.10S: The national pharmaceutical regulations provide in the list of medicines that each professional category can prescribe. However, in the absence of control, it can be estimated that all the staff prescribe all the drugs.		

Section 9 Household data/household access

9.00 Registrant Information for Section 9

9.00.01	Name of person responsible for completing this section of the instrument	
9.00.02	Phone number	
9.00.03	E-mail address	
9.00.04	Other registrants for this section	

9.01 Household survey data Basic questions

			Year	Source
9.01.01	What household surveys have been carried out in the past five years to assess access to medicines?			
9.01.02	Adults with acute conditions within two weeks of recall taking all medications prescribed by an authorized prescriber (%)			
9.01.03	Adults with acute conditions who did not take all medicines because they could not afford them (%)			
9.01.04	Adults (from poor households) with an acute medical condition within two weeks of recall taking all medications prescribed by an authorized prescriber (%)			
9.01.05	Adults (from poor households) with an acute condition within two weeks of recall not having taken all medications due to lack of means to purchase them (%)			

9.01.06	Adults with chronic conditions who took all medications prescribed by an authorized prescriber (%)			
9.01.07	Adults (from poor households) with chronic conditions who did not take all prescribed drugs because they could not afford them (%)			
9.01.08	Adults (from poor households) with chronic conditions who usually took all medications prescribed by an authorized prescriber (%)			
9.01.09	Children (from poor households) with an acute condition within two weeks of recall taking all medications prescribed by an authorized prescriber (%)			
9.01.10	Percentage of people who obtained the prescribed medication in the 15 days preceding the interview (%)			
9.01.11	People who obtained free prescribed drugs in the 15 days preceding the interview (%)			
9.01.12	Comments & bibliographical references	Section 9: This section has not been completed. The last household survey dates back to 2002. It was entitled "Comprehensive survey on the consumption of goods and services" by the Ministry of Planning.		
Additional Questions				
			Year	Source
9.01.13S	Adults with ailments not taking all medications because they were not available (%)			
9.01.14S	Adults with chronic conditions who have not taken all the drugs due to lack of means			

	to buy them (%)			
9.01.15S	Adults with ailments patients who did not take all the drugs because they were not available (%)			
9.01.16S	Children with ailments having taken all medications prescribed by an authorized prescriber (%)			
9.01.17S	Children with acute conditions who did not take all the drugs because they could not afford them (%)			
9.01.18S	Children with ailments not taking all medications because they were not available (%)			
9.01.19S	Children (from poor households) suffering from acute conditions who did not take all the medicines because they could not afford them (%)			
9.01.20S	Comments & references bibliographic			

ESSENTIAL DOCUMENTS TO ATTACH

Document	Exact title	Author	Publisher	Year	Name of file
National drug policy (PPN)					
PPN Implementation Plan					
National pharmaceutical legislation					
National resource strategy report or plan human resources in the pharmaceutical field					
Most recent national pharmaceutical market report (regardless of source)					
National pharmacovigilance center report (including the adverse drug reaction analysis report for the past two years)					
National drug regulatory legislation					
Quality Control Laboratories Annual Report					
Quality Control Laboratories Annual Report					
National regulatory authority annual report					
Legal provisions relating to the regulation of drug prices					
Drug Purchasing Policy					
National Essential Medicines List (EML)					
Therapeutic guides National standards (GTN)					

National Antimicrobial Resistance Strategy					
All price/price surveys availability of drugs, household surveys, and rational use surveys other than those that have been used to prefill the tool.					

MANUAL FOR DATA COLLECTION

Instructions

Section 1- HEALTH AND DEMOGRAPHIC DATA

1.01 Demographic and socioeconomic indicators

In this section, the answers to the questions have been pre-populated with information from the WHO and/or World Bank databases. Please check that they are correct according to you. If you find an incorrect answer in a pre-populated field, please edit it and indicate the source and year.

If you have a value that is similar to the pre-filled field but more recent, please edit it and include the source and year.

Possible sources of information

- Ministry of Health

- Ministry of Planning

- National Bureau of Statistics

- Useful websites:

http://www.who.int/gho/en/ The WHO Global Health Observatory site provides recent and comprehensive health data on all WHO Member States The data, selected on the basis of their quality, availability, relevance to the global health and the possibilities they offer for comparability between Member States, cover more than 50 health indicators classified in six main areas: mortality and

burden of disease, coverage of health services, risk factors, resources available to the health system, differences in health outcomes and coverage, basic socio-demographic statistics. They are published annually in World Health Statistics in May.

http://www.who.int/infobase/report.aspx The WHO Global InfoBase is a database that collects, stores and disseminates information on chronic diseases and their risk factors for all WHO Member States.

http://unstats.un.org/unsd/demographic/products/socind/default.htm The UN social indicators, which cover a wide range of areas, are compiled on the basis of data collected from numerous national and international sources by the Statistics Division of the Department of Economic and Social Affairs of the United Nations Secretariat.

http://siteresources.worldbank.org/INTWDR2009/Resources/ 4231006-1225840759068/WDR09_22_SWDIweb.pdf _ The World Bank's 2009 Development Report provides recent data for most country profile indicators.

http://world-gazetteer.com/ The World Gazetteer makes available a comprehensive set of demographic data and related statistics. Demographic data is presented by country. In particular, the number of inhabitants and the area of administrative divisions, main localities, cities and territories, and metropolitan areas are specified. Historical demographic data (from censuses or estimates, from the last or penultimate census) are also provided.

1.02 - Life expectancy, morbidity and causes of death

In this section, the answers to the questions have been pre-populated with data from the WHO and/or World Bank databases. Please check that they are correct according to you. If you find an incorrect answer in a pre-populated field, please edit it and indicate the source and year.

If you have a value that is similar to the pre-filled field but more recent, please edit it and include the source and year.

Possible sources of information

- Ministry of Health

- Ministry of Planning

- National Bureau of Statistics

- Useful websites, in addition to those listed in the previous section:

http://www.who.int/healthinfo/bod/en/index.html The WHO Global Burden of Disease and Risk Factors Database provides mortality and disease burden (DALY) statistics, categorized by cause, for the world, regions and Member States of the World. 'Organization. Here you can find estimates of life expectancy and healthy life expectancy in Member States, documents, methods, results and projections relating to the global burden of disease, as well as software to conduct national studies on the burden of disease.

http://www.measuredhs.com/aboutsurveys/start.cfm The Demographic and Health Surveys (DHS) project allows for a wide range of data collection possibilities, depending on particular monitoring and evaluation needs. It consists of several parts.
Demographic and Health Surveys (DHS) provides data on many indicators for monitoring and evaluating impact in the areas of demography, health and nutrition. **AIDS Indicator Surveys (AIS)** provide countries with a standardized tool for obtaining indicators for effective monitoring of national HIV/AIDS programs. **Service Provision Assessment (SPA) Surveys** provide information on the characteristics of health and family planning services available in the country. **Key Indicators Survey (KIS)** provides monitoring and evaluation data on demographics and health activities in small areas – regions, districts, catchment areas.

They can be used in the context of an isolated project, but also in studies of national scope. The **Other Quantitative Surveys** component encompasses the collection of biomarkers and geographic data and comparative studies.

Basic Questions

1.02.06 **List the top 10 killer diseases**

This information is available from your national statistics office. The degree of precision with which diseases are defined varies by country. Please use the most accurate and recent list in your response. If applicable, indicate the URL of your source in the Comments section.

1.02.07 **List the top 10 diseases causing morbidity**

This information is available from your national statistics office. The degree of precision with which diseases are defined varies by country. Please use the most accurate and recent list in your response. If applicable, indicate the URL of your source in the Comments section.

Section 2 - HEALTH SERVICES

2.01 Health expenditure

The answers to some of the questions are already in the pre-filled fields. When this is the case, please check that they are correct in your opinion. If you find an incorrect answer in a pre-populated field, please edit it and indicate the source and year.

If the value of the pre-filled field is close to your national sources but it is older, please modify it with the most recent data, for which you will indicate the source and the year.

Possible sources of information

Ministry of Health

Ministry of Finance

Ministry of Planning

National Bureau of Statistics

Useful websites :

http://www.who.int/nha/en/ The WHO National Health Accounts (NHA) provide information to track trends in health expenditure in a country.
The data cover all sectors (public and private), different health activities and different providers, diseases, population groups and regions of countries. They are intended to help develop effective national health financing strategies and find additional funds. They can be used to make financial projections on the needs of a national health system or to draw comparisons with the past situation or with the experience of other countries.

http://www.who.int/macrohealth/en/ The national macroeconomic and health reports presented at this address provide information on the state of health, health systems and the financing of health care. They also deliver an analysis of health care costs and health investment plans.

http://unstats.un.org/unsd/snaama/introduction.asp The Economic Statistics Branch of the United Nations Statistics Division maintains a database of national accounts statistics where the main country aggregates can be found. This database is the result of cooperation between the United Nations Statistics Division, international statistical agencies and the national statistical offices of more than 200 countries. It responds to the request of the Statistical Commission, which had expressed the wish that

regularly disseminated the most recent national accounts data from as many countries and territories as possible.

http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.4/clmd,50.html#hlCL1_1_1_2_4

The Online Library of WHO Medicines Publications and Documents contains over 500 titles in English, French and Spanish. Most of them come from a wide range of mainly technical documentary resources. This link directs you directly to the documents relating to drug financing.

http://apps.who.int/medicinedocs/en/d/Js6160e/6.html This link allows you to consult Chapter 4 of the WHO World Medicines Situation Report (2004), devoted to the world sales and consumption of pharmaceutical products. This chapter presents drug expenditures for many countries, based on consumption estimates and sales analysis.

Basic Questions

2.01.09 **Population covered by a public health service, public health insurance, social health insurance or other health insurance fund (% of total population)**

This data must be communicated to you by your government. It is expressed as a percentage of the total population. If there is a public health system in your country and everyone has access to it, the answer is “100%”. If some groups have more than one coverage, be careful not to count them more than once so as not to arrive at a result greater than 100%.

2.01.10 **Population covered by private health insurance (% of total population)**

This data must be communicated to you by your government. It is expressed as a percentage of the total population. Private health insurance covers both for-profit and non-profit (community-based health insurance) insurance systems.

Additional Questions

2.01.21 **Generic Pharmaceuticals [Branded and INN] Market Share** by Value (%)

Report here the market share of all generics, including brand name and INN generics. This share is expressed as a percentage of the value of the overall pharmaceutical retail market in your country, which includes public and private markets and, where applicable, reimbursement.

2.01.22 **Pharmaceuticals Total Market Value YoY Growth Rate (%)**

This data can be obtained from your government or local manufacturers association. Please use the most recent value and do not average over several years.

2.01.23 **Generic Pharmaceuticals Market YoY Growth Rate (%)**

This data can be obtained from your government or local manufacturers association. Please use the most recent value and do not average over several years.

2.02 Health personnel and infrastructure

The answers to some of the questions are already in the pre-filled fields. When this is the case, please check that they are correct in your opinion. If you find an incorrect answer in a pre-populated field, please edit it and indicate the source and year.

If the value of the pre-filled field is close to your national sources but it is older, please modify it with the most recent data, of which you will indicate the source and
the year.

Possible sources of information

Ministry of Health

Ministry of Finance

Ministry of Planning

National Bureau of Statistics

Useful websites:

http://www.who.int/gho/en/ The Global Health Observatory (GHO) is an interactive database that brings together essential health statistics from all 193 WHO Member States. It encompasses over 100 indicators that can be viewed through a quick search, by broad categories, or through user-defined tables.

Data can be filtered, presented in tables or graphs, and downloaded. They are published each year in World Health Statistics, in May.

http://apps.who.int/globalatlas/default.asp In particular, the World Health Atlas contains more detailed data on the health workforce of WHO Member States.

http://www.who.int/macrohealth/en/ The national macroeconomic and health reports presented at this address provide information on health status, health systems, health personnel and financing of care as well as an analysis of health care costs and investment plans sanitary.

http://unstats.un.org/unsd/snaama/introduction.asp The Economic Statistics Branch of the United Nations Statistics Division maintains a database of national accounts statistics where the main country aggregates can be found. This database is the result of cooperation between the United Nations Statistics Division, international statistical agencies and the national statistical offices of more than 200 countries. It responds to the request made by the Statistical Commission for the regular release of the most recent national accounts data from as many countries and territories as possible.

Basic Questions

2.02.01 **Total number of pharmacists licensed to practice in your country**

In some countries, pharmacists must regularly renew their license to practice. This question aims to know the number of pharmacists whose authorization to practice is up-to-date and legally valid. Information can be obtained from the Council of Pharmacists, if there is one, or failing that, from the Ministry of Health. If you are unable to find out the number of pharmacists with a valid authorization to practice, please indicate the number of registered pharmacists and specify it in the comments.

2.02.03 **Total number of pharmacists in the public sector**

This figure includes pharmacists who work in government, hospitals and other public institutions, as well as manufacturers, wholesalers and medical supply stores when they are in the public sector. It does not include pharmacists who work in private pharmacies that have entered into a service contract with the government. This data can be obtained from your government or, failing that, from the Council of Pharmacists, if there is one.

2.02.04 **Total number of pharmacy technicians and assistants**

Information can be obtained from the Council of Pharmacists, if there is one, or failing that, from the Ministry of Health.

Manual

2.02.05 **Is there a strategic plan for the development of human resources in pharmacy in your country?**

Yes	Such a plan exists. Please attach a copy to your completed questionnaire and provide the URL if available. If pharmacy human resource development is part of a broader health human resource plan, please answer yes and provide explanation in the comments field.
No	Answer to be given in all other cases.

2.02.13 **Total number of licensed pharmacies in your country**

Information can be obtained from the Council of Pharmacists, if there is one, or failing that, from the Ministry of Health.

Additional Questions

2.02.15 **Net annual starting salary of a newly graduated pharmacist in the public sector, in national currency (UMN)**

This data, expressed in national currency, must be communicated to you by your government. It is linked to the annual net income.

2.02.16 **Total number of pharmacists having obtained their diploma (basic diploma) these last two years**

For consistency, add the figures for the last two full years prior to the study. If you are unable to obtain this data, you can indicate the number of pharmacists who have registered in the last two years. Please specify this in the comments field.

Section 3 - PHARMACEUTICAL POLICIES

The answers to some of the questions are already in the pre-filled fields. When this is the case, please check that they are correct in your opinion. If you find an incorrect answer in a pre-populated field, please edit it and indicate the source and year.

If the value of the pre-filled field is close to your national sources but it is older, please modify it with the most recent data, for which you will indicate the source and the year.

3.01 Policy Outline

Possible sources of information

- Ministry of Health

- National legislative documents

- Drug regulatory authority, if any

- Useful websites:

http://apps.who.int/medicinedocs/en/cl/CL1.1.1.1.2/clmd,50.html#hlCL1_1_1_1_2

The Online Library of WHO Medicines Publications and Documents contains over 500 titles in English, French and Spanish. Most of them come from a wide range of mainly technical documentary resources. This link directs you directly to the documents relating to the pharmaceutical policy, which are often useful.

http://apps.who.int/medicinedocs/fr/cl/CL6.1.1.18.19/clmd,50.html#hlCL6_1_1_18_19

This link directs you to the WHO online library with direct links to often relevant right to health documents.

http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.5/clmd,50.html#hlCL1_1_1_2_5

This link directs you to the WHO online library, directing you directly to documents related to good governance in pharmaceutical practices, which are often useful
for you.

Basic Questions

Manual

3.01.01 **There is a national health policy.**

Yes	There is a national health policy and it is presented in a document made available to all. Then specify the year of its latest version in the "year" field and indicate the URL if it is available.
No	Answer to be given in all other cases.

3.01.02 **There is a national health policy implementation plan.**

Yes	There is an implementation plan for the national health policy and it is presented in a document made available to all. Then specify the year of its latest version in the "year" field and indicate the URL if it is available. The "implementation plan" designates any strategic operational plan aimed at ensuring the proper application of the national health policy.
No	Answer to be given in all other cases.

3.01.04 **There is an official document relating to the national pharmaceutical policy.**

Yes	There is a national pharmaceutical policy and it is presented in an official document made available to all. Then specify the year of its latest version in the "year" field, attach a copy of the document to your completed questionnaire and indicate the URL if it is available.
No	Answer to be given in all other cases.

3.01.05 **There is a group of policies concerning pharmaceutical products.**

Yes	Answer to be given if there is a group of pharmaceutical policies, even if they are not consolidated into an overall national pharmaceutical policy document. Please attach a copy of the document to your completed questionnaire and provide the URL if available.
No	Answer to be given in all other cases.

3.01.07 There is an **implementation plan for the national pharmaceutical policy.**

Yes	There is an implementation plan for the national pharmaceutical policy and it is presented in a document made available to all. Then specify the year of its latest version in the "year" field, attach a copy of the document to your completed questionnaire and indicate the URL if it is available. The "implementation plan" refers to any strategic operational plan aimed at ensuring the proper application of the national pharmaceutical policy.
No	Answer to be given in all other cases.

3.01.12 **Is the implementation of the pharmaceutical policy regularly monitored/ evaluated ?**

Yes	Answer to be given if there is a tangible follow-up process that produces concrete results. To be considered regular, evaluations must be at least quarterly.
No	Answer to be given in all other cases.

3.01.13.01 & 3.01.13.02 **If there is a national good governance policy, specify its scope (multisectoral/pharmaceutical sector only).**

3.01.12.01	“Yes” if the policy concerns all sectors of the State.
3.01.12.02	“Yes” if there is a separate policy for the pharmaceutical sector.

Section 4 - TRADE AND PRODUCTION OF MEDICINES

4.01 Intellectual property rights and medicines The answers to some of the questions are already in the pre-filled fields. When this is the case, please check that they are correct in your opinion. If you find an incorrect answer in a pre-populated field, please edit it and indicate the source and year.

If the value of the pre-filled field is close to your national sources but it is older, please modify it with the most recent data, of which you will indicate the source and the year.

Possible sources of information

Ministry of Health

Ministry of Finance

Department of Commerce

national patent office

Useful websites:

http://www.who.int/phi/en/ This link takes you to the page of the WHO website relating to the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG), where recent data on intellectual property rights are disseminated intellectual and medication.

http://www.wto.org/french/thewto_f/whatis_f/tif_f/org6_f.htm This link takes you directly to the list of WTO members and classified international trade information by country.

http://www.wto.org/french/tratop_f/trips_f/factsheet_pharm00_f.htm This link takes you directly to the content of the Fact Sheet on the TRIPS Agreement and Pharmaceutical Patents, on the WTO website.

4.02 Manufacturing

Possible sources of information

Ministry of Health

Ministry of Finance

Ministry of Industry

Department of Commerce

Drug regulatory authority

Manufacturers Associations

IMS Country Reports

Basic Questions

4.02.01 **Number of licensed pharmaceutical manufacturers in the country**

The figure includes manufacturers registered in your country (both local businesses and multinational corporations). This data is, as we know, difficult to obtain in large decentralized countries such as India.

Additional Questions

4.02.05 **Percentage of market share by volume produced by domestic manufacturers (%)**

This data can be obtained from your government or, if applicable, the national manufacturers association. It may be difficult to obtain in some countries.

Manual

4.02.07 **Number of manufacturers having obtained the GMP certificate**

This data can be obtained from your government. The drug regulatory authority, if it exists, might also have this information.

Section 5 - PHARMACEUTICAL REGULATIONS

The answers to some of the questions are already in the pre-filled fields. When this is the case, please check that they are correct in your opinion. If you find an incorrect answer in a pre-populated field, please edit it and indicate the source and year.

If the value of the pre-filled field is close to your national sources but it is older, please modify it with the most recent data, for which you will indicate the source and the year.

5.01 Regulatory Framework

Possible sources of information

- Ministry of Health

- Drug regulatory authority, if any

- Useful websites:

http://apps.who.int/medicinedocs/en/cl/CL1.1.1.1.2/clmd,50.html - hlCL1_1_1_1_2 http://apps.who.int/medicinedocs/en/cl/CL1.1.1.5.5 /clmd,50.html#hlCL1_1_1_5_5

The Online Library of WHO Medicines Publications and Documents contains over 500 titles in English, French and Spanish. Most of them come from a wide range of mainly technical documentary resources. This link takes you directly to the often useful regulatory support documents.

http://apps.who.int/medicinedocs/fr/cl/CL1.1.1.2.5/clmd,50.html#hlCL1_1_1_2_5

This link directs you to the WHO online library, directing you directly to documents relating to good governance in pharmaceutical practice, which are often relevant.

http://www.ich.org/cache/compo/276-254-1.html This link takes you to the official website of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). You can find the ICIDH guidelines there as well as several other interesting documents.

Basic Questions

Manual

5.01.01 **There are legislative provisions establishing the powers and responsibilities of the drug regulatory authority.**

Yes	Answer to be given if such legislative provisions exist. Attach a copy of the national drug law to your completed questionnaire.
No	Answer to be given in all other cases.

5.01.04 **If there is a medicines regulatory authority, it:**

5.01.04.01	Part of the Ministry of Health. Answer to be given when the employees of the national regulatory authority are employed by the ministry of health and the budget items of the body are placed under the direct control of that ministry. Authority does not necessarily have its seat in the ministry.
5.01.04.02	Is a semi-autonomous body. Answer to be given if the staff members of the national regulatory authority are not assimilated to civil servants, even if the government exerts influence on the body by being present on the management committee.
5.01.04.03	Other: Answer to be given if the authority is not part of the Ministry of Health nor is it a semi-autonomous body. If so, please describe its structure.

5.01.07 **The drug regulatory authority has its own website.**

Yes	If so, please provide its URL in question 5.01.07.01.
No	Answer to be given in all other cases.

5.01.12 **The drug regulatory authority is funded by payment for services provided.**

Yes	Answer to be given if a system of paying services is in place.
No	Answer to be given in all other cases.

5.01.14 **Revenue from regulatory activities is retained by the regulatory authority**

Yes	Whether the authority retains revenue from its activities (payments for services, for example).
No	If the proceeds go to the state.

5.01.15 **The regulator uses a computerized information management system to store and retrieve data relating to approvals, inspections, etc.**

Yes	Whether the authority uses a computerized information management system to process some of the regulatory information it receives and produces.
No	Answer to be given in all other cases.

5.02 Marketing Authorization (Approval)

Possible sources of information

- Ministry of Health

- Drug regulatory authority, if any

Manual

- Useful websites:

http://apps.who.int/medicinedocs/fr/cl/CL6.2.1.1.32/clmd,50.html#hlCL6_2_1_1_32___

The Online Library of WHO Medicines Publications and Documents contains over 500 titles in English, French and Spanish. Most of them come from a wide range of mainly technical documentary resources. This link directs you
directly to the documents relating to the marketing authorization .

http://apps.who.int/medicinedocs/en/m/abstract/Js16234e/ This address refers directly to the document “WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No.

014” (2008, only in English). This document, drawn up by the WHO, brings together various tools aimed at supporting the work of national drug regulatory authorities and helping them in their decisions.

Basic Questions

5.02.07.01 **If a list of** approved **pharmaceutical products is regularly published, please specify how often the document is updated.**

Please indicate the effective time interval between the last two versions of the document.

Additional Questions

5.02.17 **Value of the registration fee: amount per application for a pharmaceutical product containing a new chemical entity (NEC), in US$.**

Please specify the value of the registration fee in US$. Please use the exchange rate in effect at the time you complete the survey. Indicate the rate and date in the comments field.

5.02.18 **Value of the registration fee: amount per request for a generic pharmaceutical product (US$).**

Please specify the value of the registration fee in US$. Please use the exchange rate in effect at the time you complete the survey. Indicate the rate and date in the comments field.

5.03 Regulatory inspection

Possible sources of information

- Ministry of Health

- Drug regulatory authority, if any

- Useful websites:

http://apps.who.int/medicinedocs/fr/cl/CL6.2.1.1.29/clmd,50.html#hlCL6_2_1_1_294

The Online Library of WHO Medicines Publications and Documents contains over 500 titles in English, French and Spanish. Most of them come from a wide range of mainly technical documentary resources. This link takes you directly to the quality assurance documents.

http://apps.who.int/medicinedocs/documents/s14136e/s14136e.pdf

This address is a link to the document “WHO Quality assurance of pharmaceuticals A compendium of guidelines and related materials. Volume 2, 2nd updated edition. Good manufacturing practices and inspection” (only the first volume is available in French). This comprehensive document contains a section entirely devoted to inspections in the medicine supply chain.

Basic Questions

5.03.04 **Public establishments and private establishments are subject to the same inspection requirements**

Yes	Answer to be given when there are inspection requirements and they are identical in public and private establishments.
No	Answer to be given in all other cases.

5.04 Import Control

Possible sources of information

- Ministry of Health

- Drug regulatory authority, if any

- Useful websites:

http://apps.who.int/medicinedocs/fr/cl/CL6.2.1.1.29/clmd,50.html#hlCL6_2_1_1_29

The Online Library of WHO Medicines Publications and Documents contains over 500 titles in English, French and Spanish. Most of them come from a wide range of mainly technical documentary resources. This link takes you directly to the quality assurance documents.

http://apps.who.int/medicinedocs/en/m/abstract/Js16234e/ This address refers directly to the document “WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014” (2008, English only). This document, drawn up by the WHO, brings together various tools aimed at supporting the work of national drug regulatory authorities and helping them in their decisions.

5.05 Grant of Licenses

Possible sources of information

- Ministry of Health

- Drug regulatory authority, if any

- Useful websites:

http://apps.who.int/medicinedocs/fr/cl/CL6.2.1.1.29/clmd,50.html#hlCL6_2_1_1_29

The Online Library of WHO Medicines Publications and Documents contains over 500 titles in English, French and Spanish. Most of them come from a wide range of mainly technical documentary resources. This link takes you directly to the quality assurance documents.

http://apps.who.int/medicinedocs/en/m/abstract/Js16234e/ This address refers directly to the document “WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014” (2008, English only). This document, drawn up by the WHO, brings together various tools aimed at supporting the work of national drug regulatory authorities and helping them in their decisions.

5.6 Market Control and Quality Control

Possible sources of information

- Ministry of Health

- Drug regulatory authority, if any

- Useful websites:

http://apps.who.int/medicinedocs/fr/cl/CL6.2.1.1.29/clmd,50.html#hlCL6_2_1_1_29

The Online Library of WHO Medicines Publications and Documents contains over 500 titles in English, French and Spanish. Most of them come from a wide range of mainly technical documentary resources. This link directs you directly to the often useful quality assurance documents.

http://apps.who.int/medicinedocs/fr/cl/CL6.2.1.16.38/clmd,50.html#hlCL6_2_1_16_38

This link directs you directly to the documents relating to pharmacovigilance, which are often relevant.

http://apps.who.int/medicinedocs/en/m/abstract/Js16234e/ This address refers directly to the document “WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014” (2008, English only). This document, drawn up by the WHO, brings together various tools aimed at supporting the work of national drug regulatory authorities and helping them in their decisions.

5.07 Drug Advertising and Drug Promotion

Possible sources of information

- Ministry of Health

- Drug regulatory authority, if any

- National Association of Manufacturers, if any

- Consumer associations

- NGO

- Useful websites:

http://apps.who.int/medicinedocs/en/cl/CL6.1.1.16.45/clmd,50.html#hlCL6_1_1_16_45

The Online Library of WHO Medicines Publications and Documents contains over 500 titles in English, French and Spanish. Most of them come from a wide range of mainly technical documentary resources. This link directs you directly to documents relating to pharmaceutical promotion, which are often useful.

http://www.drugpromo.info/ This link allows you to access a database containing a wide range of documents which describe, analyze, inform or offer comments on the various aspects of pharmaceutical promotion. This is part of a WHO/Health Action International project on drug promotion.

http://apps.who.int/medicinedocs/pdf/s8109e/s8109e.pdf This link gives you direct access to an analysis of the WHO/HAI database: "Drug promotion what we know, what we have yet to learn - Reviews of materials in the WHO/HAI database on drug promotion".

Basic Questions

5.07.04 **There are legal provisions that require advertising and promotional materials for medicines to obtain prior approval.**

Yes	Pre-approval of advertising and promotional materials means that the drug regulatory authority must review and approve them before they can be used, to ensure that their content is accurate and not misleading. Response to be given if such legislative provisions exist.
No	Answer to be given in all other cases.

5.08 Clinical Trials

Possible sources of information

- Ministry of Health

- Drug regulatory authority, if any

- Useful websites:

http://apps.who.int/medicinedocs/en/cl/CL1.1.1.5.6/clmd,50.html#hlCL1_1_1_5_6

The Online Library of WHO Medicines Publications and Documents contains over 500 titles in English, French and Spanish. Most of them come from a wide range of mainly technical documentary resources. This link takes you directly to the often helpful safety and effectiveness documents.

http://apps.who.int/medicinedocs/documents/s14084e/s14084e.pdf This link gives you direct access to the WHO Good Clinical Practice Guidelines. This very useful document serves as a reference and educational tool to facilitate the proper understanding and implementation of Good Clinical Practices (GCP):

• describing the clinical research process relating to medical and health products, describing and explaining each of the activities common to most trials and specifying which parties are generally responsible for carrying them out;

• linking each of these processes to one or more GCP principle(s);

• explaining each of these principles and giving advice on how to apply them systematically;

• directing the reader to international recommendations and other references offering more specific advice on how best to join.

http://apps.who.int/tdr/publications/training-guideline-publications/operational-guidelines ethics-biomedical-research/pdf/ethicsen.pdf This link gives you direct access to the Operational guidelines for ethics committees responsible for the evaluation of biomedical research.

5.09 Restricted drugs The answers to some of the questions are already in the pre-populated fields. When this is the case, please check that they are correct in your opinion. If you find an incorrect answer in a pre-populated field, please edit it and indicate the source and year.

If the value of the pre-filled field is close to your national sources but it is older, please modify it with the most recent data, for which you will indicate the source and the year.

Possible sources of information

- Ministry of Health

- Useful websites:

http://www.incb.org This is the website of the International Narcotics Control Board (INCB), an independent and quasi-judicial UN control body responsible for monitoring the application of the international drug control treaties. It was established in 1968, pursuant to the Single Convention on Narcotic Drugs of 1961. Most of the information collected in this section can be found on the INCB website.

http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2/clmd,50.html#hlCL1_1_1_2_3

The Online Library of WHO Medicines Publications and Documents contains over 500 titles in English, French and Spanish. Most of them come from a wide range of mainly technical documentary resources. This link directs you directly to the documents relating to restricted drugs, which are often relevant.

http://www.painpolicy.wisc.edu This is the website of the University of Wisconsin Carbon Cancer Center's Pain & Policy Studies Group, a WHO Collaborating Center that offers useful international resources.

5.10 Pharmacovigilance

Possible sources of information

- Ministry of Health

- Drug Regulatory Authority

- Useful websites:

http://apps.who.int/medicinedocs/en/cl/CL6.1.1.16.22/clmd,50.html#hlCL6_1_1_16_22

The Online Library of WHO Medicines Publications and Documents contains over 500 titles in English, French and Spanish. Most of them come from a wide range of mainly technical documentary resources. This link directs you directly to the documents relating to pharmacovigilance, which are often useful.

http://www.who-umc.org This is the website of the Uppsala WHO Collaborating Center for International Pharmacovigilance (Uppsala Monitoring Centre, UMC). The center is responsible for managing the WHO program on international pharmacovigilance. The UMC is an independent scientific center of excellence that offers a wide range of products and services based on the WHO global ICSR (individual case safety report) database, compiled by health providers and patients from WHO member countries participating in the programme. It provides essential resources for regulators, healthcare professionals, researchers and the pharmaceutical industry. You can find many of these resources on the website.

5.10.04.01 **If a national pharmacovigilance center exists in your country, what is its full-time staff?**

If your country has a national pharmacovigilance centre, only count the full-time employees in all of its sites at the time of completing the questionnaire.

5.10.07 **If an adverse drug reaction database exists in**

How many adverse drug reaction reports does your country have?

This figure may be communicated by the persons in charge of maintaining the database on adverse drug reactions, generally within the national pharmacovigilance centre. For consistency, add the number of adverse drug reactions reported during the last two full years prior to the study.

5.10.08 **If an adverse drug reaction database exists in**

your country, how many adverse drug reaction reports have been received over the past two years?

This figure may be communicated by the persons in charge of maintaining the database on adverse drug reactions, generally within the national pharmacovigilance centre. For consistency, add the number of adverse drug reactions reported during the last two full years prior to the study.

5.10.09.01 **If adverse drug reaction reports have been submitted for inclusion in** the WHO **Adverse Drug Reaction database in Uppsala, how many have been submitted in the past two years?**

This figure may be communicated by the persons in charge of maintaining the database on adverse drug reactions, generally within the national pharmacovigilance centre. For consistency, select the number of adverse drug reactions reported to the WHO Collaborating Center in Uppsala during the last two full years prior to the study.

Section 6 - DRUG FUNDING

The answers to some of the questions are already in the pre-filled fields. When this is the case, please check that they are correct in your opinion. If you find an incorrect answer in a pre-populated field, please edit it and indicate the source and year.

If the value of the pre-filled field is close to your national sources but it is older, please modify it with the most recent data, for which you will indicate the source and the year.

6.01 Pharmacy Benefits and Exemptions

Possible sources of information

Ministry of Health

Ministry of Finance

Ministry of Planning

National Bureau of Statistics

National or public health insurance system

Useful websites:

http://apps.who.int/medicinedocs/en/cl/CL6.2.1.6.2/clmd,50.html#hlCL6_2_1_6_2

The Online Library of WHO Medicines Publications and Documents contains over 500 titles in English, French and Spanish. Most of them come from a wide range of mainly technical documentary resources. This link directs you

directly to the documents relating to drug financing.

http:// siteresources.worldbank.org/ INTHSD/ Resources/ topics/ Health-Financing/ HFRFull.pdf This link takes you to the World Bank publication: *A practitioner's guide: Health Financing Revisited* (2006) which provides useful information on different health insurance systems.

6.02 Payment by patients and copayment by patients

Possible sources of information

Ministry of Health

Ministry of Finance

Ministry of Planning

National Bureau of Statistics

National or public health insurance system

Useful websites:

http://apps.who.int/medicinedocs/en/cl/CL6.2.1.6.2/clmd,50.html#hlCL6_2_1_6_2

The Online Library of WHO Medicines Publications and Documents contains over 500 titles in English, French and Spanish. Most of them come from a wide range of mainly technical documentary resources. This link directs you directly to the documents relating to drug financing.

http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html This link takes you to an OECD health policy publication, *Medicine Prices in a Global Market,* which provides useful information on medicine pricing policies and reimbursement practices.

6.03 Price regulation in the private sector

In this section, the private sector does not include not-for-profit organizations.

Possible sources of information

Ministry of Health

Ministry of Finance

Ministry of Planning

National Bureau of Statistics

Useful websites:

http://www.haiweb.org/medicineprices/ This link takes you to the Health Action International website, directly to the medicine pricing section where you can find comprehensive information on this topic, including the HAI-WHO manual, Measuring Price, Availability, Affordability and components of medicine prices (second edition).

http://apps.who.int/medicinedocs/en/cl/CL6.2.1.6.2/clmd,50.html#hlCL6_2_1_6_2

The Online Library of WHO Medicines Publications and Documents contains over 500 titles in English, French and Spanish. Most of them come from a wide range of mainly technical documentary resources. This link directs you directly to the documents relating to drug financing.

http:// www.oecd.org/ document/ 36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html This link takes you to an OECD health policy publication, *Medicine Prices in a Global Market,* which provides useful information on medicine pricing policies and reimbursement practices.

6.04 Pricing, Availability and Affordability

Possible sources of information

Ministry of Health

Ministry of Finance

Ministry of Planning

Department of Commerce

Useful websites:

http://www.haiweb.org/medicineprices/ This link takes you to the Health Action International website, directly to the medicine pricing section where you can find comprehensive information on this topic, including the HAI-WHO handbook, Measuring Price, Availability, Affordability and components of medicine prices (second edition).

http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=DMP&language=English

This link provides direct access to the International Drug Price Indicator Guide, published by Management Sciences for Health (MSH)

http://apps.who.int/medicinedocs/en/cl/CL6.2.1.6.2/clmd,50.html#hlCL6_2_1_6_2

The Online Library of WHO Medicines Publications and Documents contains over 500 titles in English, French and Spanish. Most of them come from a wide range of mainly technical documentary resources. This link directs you directly to the documents relating to drug financing.

Manual

6.04.01 **Please indicate if a medicine price survey using the WHO/HAI method has been carried out in your country in the past 5 years.**

Yes	If yes, please indicate the year of the survey and use its results to complete this table.
No	Answer to be given in all other cases. If the answer is negative and other surveys on drug prices and availability have been carried out, *do not use them,* but give some of their results in the comments field and attach the corresponding reports to the questionnaire.

WHO will pre-populate this table with the results of the WHO/ HAI medicine price survey, if available.

If you are aware of any reports containing similar data obtained using a different method, please attach a copy to your completed questionnaire and provide the URL if available.

6.05 Price Components and Affordability

Possible sources of information

Ministry of Health

Ministry of Finance

Ministry of Planning

Department of Commerce

Useful websites:

http://www.haiweb.org/medicineprices/ This link takes you to the Health Action International website, directly to the medicine pricing section where you can find comprehensive information on this topic, including the HAI-WHO handbook, Measuring Price, Availability, Affordability and components of medicine prices (second edition).

http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=DMP&language=English

This link provides direct access to the International Drug Price Indicator Guide, published by Management Sciences for Health (MSH)

http://apps.who.int/medicinedocs/en/cl/CL6.2.1.6.2/clmd,50.html#hlCL6_2_1_6_2

The Online Library of WHO Medicines Publications and Documents contains over 500 titles in English, French and Spanish. Most of them come from a wide range of mainly technical documentary resources. This link directs you directly to the documents relating to drug financing.

WHO will pre-populate this table with the results of the WHO/ HAI medicine price survey, if available.

If you are aware of any reports containing similar data obtained using a different method, please attach a copy to your completed questionnaire and provide the URL if available.

6.06 Duties and taxes on pharmaceutical products (market)

Possible sources of information

Ministry of Health

Ministry of Finance

Department of Commerce

Useful websites:

http://www.haiweb.org/medicineprices/ This link takes you to the Health Action International website, directly to the medicine pricing section where you can find comprehensive information on this topic, including the HAI-WHO handbook, Measuring Price, Availability, Affordability and components of medicine prices (second edition).

Section 7 - PURCHASE AND DISTRIBUTION OF PRODUCTS PHARMACEUTICALS

The answers to some of the questions are already in the pre-filled fields. When this is the case, please check that they are correct in your opinion. If you find an incorrect answer in a pre-populated field, please edit it and indicate the source and year.

If the value of the pre-filled field is close to your national sources but it is older, please modify it with the most recent data, for which you will indicate the source and the year.

7.01 Pharmaceutical purchases in the public sector

Possible sources of information

- Ministry of Health

- Public purchasing body

- Public hospitals and dispensaries

- Useful websites:

http://apps.who.int/medicinedocs/en/cl/CL1.1.2.2.8/clmd,50.html#hlCL1_1_2_2_8

The Online Library of WHO Medicines Publications and Documents contains over 500 titles in English, French and Spanish. Most of them come from a wide range of mainly technical documentary resources. This link directs you directly to the documents relating to supply management, which are often useful.

http://apps.who.int/medicinedocs/en/cl/CL1.1.1.6.1/clmd,50.html#hlCL1_1_1_6_1

This link takes you to the WHO online library, taking you directly to the section on prequalification of medicines, where you will find several essential documents on procurement.

Basic Questions

7.01.01.01 **Public sector procurement is decentralized.**

Yes	Answer to be given when the responsibility for purchasing rests with the administrative regions, provinces or districts, or directly with the health establishments.
No	Response to be given when overall responsibility for pharmaceutical procurement rests with a public procurement agency, although it may be delegated in part to international procurement agencies in the case of specific diseases (malaria, AIDS, tuberculosis) or , from time to time, to public health establishments (in case of stock shortage, etc.)

7.01.01.02 **Public sector procurement is both centralized and decentralized.**

Yes	Response to be given when overall responsibility for pharmaceutical procurement rests with a national procurement agency, but is partly delegated to administrative regions, provinces or districts, or directly to health facilities.
No	Answer to be given in all other cases.

7.01.02 **If public sector procurement is totally or partially centralized, it is the responsibility of a procurement body which:**

7.01.02.01 **Part of the Ministry of Health**	Answer to be given when the employees of the purchasing agency are employed by the ministry of health and the budget items of the agency are placed under the direct control of the said ministry. Authority does not necessarily have its seat in the ministry.
7.01.02.02 **Is semi-autonomous**	Answer to be given when the national purchasing body is a body whose employees are not civil servants, but within which the government retains responsibilities
7.01.02.03 **Is autonomous**	Answer to be given when the organization is completely independent of the government. It can be a for-profit or non-profit organization (non-governmental organization)
7.01.02.04 **Is a state agency that purchases all property for public use**	Answer to be given when the employees of the national purchasing body are civil servants and the pharmaceutical products are acquired for use in the public sector.

7.02 Distribution of pharmaceutical products in the public sector

Possible sources of information

- Ministry of Health

- Department of Commerce

- Public purchasing body

- Central medical warehouse

- Warehouses of administrative regions

- Public hospitals and dispensaries

- Drug procurement and distribution *mapping* project (ongoing WHO project).

Basic Questions

7.02.02 **Number of public warehouses at the secondary level of public distribution (national/regional/ provincial)**

When there is one warehouse per administrative region, there must be as many answers as there are administrative regions. If there is no secondary level of public distribution, ie. that the pharmaceutical products are transported directly from the central management service to the place of dispensing, please answer 0.

7.03 Distribution of pharmaceutical products in the private sector

Possible sources of information

- Ministry of Health

- Department of Commerce

- Consumer associations

- Associations of pharmacists

Section 8 - SELECTION AND RATIONAL USE OF MEDICATIONS

The answers to some of the questions are already in the pre-filled fields. When this is the case, please check that they are correct in your opinion. If you find an incorrect answer in a pre-populated field, please edit it and indicate the source and year.

If the value of the pre-filled field is close to your national sources but it is older, please modify it with the most recent data, for which you will indicate the source and the year.

8.01 National Structures

Possible sources of information

- Ministry of Health

- Public hospitals and dispensaries

- Useful websites:

http://apps.who.int/medicinedocs/en/cl/CL1.1.2.2.6/clmd,50.html#hlCL1_1_2_2_6

The Online Library of WHO Medicines Publications and Documents contains over 500 titles in English, French and Spanish. Most of them come from a wide range of mainly technical documentary resources. This link directs you directly to the documents relating to the rational use of medicines, which are often useful

for you.

http://www.inrud.org/ The International Network for Rational Use of Drugs (INRUD) was established in 1989 to design, test and disseminate effective strategies to improve the way medicines are prescribed, dispensed and used, with a focus on resource-poor countries.

Basic Questions

8.01.08 **A public or independently funded national drug information center provides drug information to prescribers, community pharmacists and consumers.**

Yes	Answer to be given only when such a drug information center exists and is financed either by public funds or by private bodies which do not derive any financial benefit from the sale of drugs.
No	Answer to be given in all other cases.

8.01.09 **Public education campaigns on the rational use of medicines have been organized over the past two years.**

Yes	Answer to be given only when such campaigns have been organized during the past two years and they did not advertise drugs.
No	Answer to be given in all other cases.

8.02 Limitation

Possible sources of information

- Ministry of Health

- Public hospitals and dispensaries

- Faculties of Medicine, Faculties of Pharmacy, Schools of Nursing

- Useful websites

http://apps.who.int/medicinedocs/en/cl/CL1.1.2.2.6/clmd,50.html#hlCL1_1_2_2_6

The Online Library of WHO Medicines Publications and Documents contains over 500 titles in English, French and Spanish. Most of them come from a wide range of mainly technical documentary resources. This link directs you directly to the documents relating to the rational use of medicines, which are often useful.

http://www.inrud.org/ The International Network for Rational Use of Drugs (INRUD) was established in 1989 to design, test and disseminate effective strategies to improve the way medicines are prescribed, dispensed and used, with a focus on resource-poor countries.

8.03 Dispensing of medication

Possible sources of information

- Ministry of Health

- Public hospitals and dispensaries

- Faculties of Medicine, Faculties of Pharmacy, Schools of Nursing

- Useful websites

http://apps.who.int/medicinedocs/en/cl/CL1.1.2.2.6/clmd,50.html#hlCL1_1_2_2_6

The Online Library of WHO Medicines Publications and Documents contains over 500 titles in English, French and Spanish. Most of them come from a wide range of mainly technical documentary resources. This link takes you directly to the documents on rational use of medicines, which contains many of the documents cited in the glossary.

http://www.inrud.org/ The International Network for Rational Use of Drugs (INRUD) was established in 1989 to design, test and disseminate effective strategies to improve the way medicines are prescribed, dispensed and used, with a focus on resource-poor countries.

Basic Questions

8.03.06 **In practice, although it may be prohibited, antibiotics are *sometimes* sold over the counter without a prescription.**

Yes	Response to be given when consumers sometimes do not need a prescription to buy antibiotics. The question here **is not** whether or not it is legal to sell antibiotics without a prescription, but rather to know the real situation, on the ground.
No	Answer to be given in all other cases.

8.03.07 **In practice, although it may be prohibited, injectable drugs are sometimes sold over the counter without a prescription.**

Yes	Response to be given when consumers sometimes do not need a prescription to buy injectable drugs. The question here **is not** whether or not it is legal to sell injectable products without a prescription, but rather to know the real situation, on the ground.
No	Answer to be given in all other cases.

Additional Questions

Manual

8.03.10.01 **In practice, although it may be prohibited, nurses prescribe prescription-only drugs in public sector primary health care.**

Yes	Response to be given when, to the best of your knowledge, nurses prescribe prescription-only drugs in public primary care settings. The question here **is not** whether nurses are authorized to prescribe them, but rather to know the real situation, on the ground.
No	Answer to be given in all other cases.

8.03.10.02 **In practice (although this may be prohibited), pharmacists prescribe prescription-only drugs in the public sector primary health care setting.**

Yes	Response to be given when, to the best of your knowledge, pharmacists prescribe prescription-only drugs in public primary care settings. The question here **is not** whether pharmacists are authorized to prescribe, but rather to know the real situation, on the ground.
No	Answer to be given in all other cases.

8.03.10.03 **In practice (although this may be prohibited), paramedics prescribe prescription-only drugs in public sector primary health care.**

Yes	Response to be given when, to the best of your knowledge, paramedics prescribe prescription-only drugs in public primary care facilities. The question here **is not** whether paramedics are authorized to prescribe, but rather to know the real situation, on the ground.
No	Answer to be given in all other cases.

8.03.10.04 **In practice, although it may be prohibited, personnel with less than one month's training prescribe prescription-only drugs in public sector primary health care.**

Yes	Response to be given when, to the best of your knowledge, staff members with less than one month's training prescribe prescription-only drugs in public primary care settings. The question here **is not** whether personnel with less than one month's training are authorized to prescribe, but rather to know the real situation in the field.
No	Answer to be given in all other cases.

Section 9 - HOUSEHOLD DATA/ ACCESS OF HOUSEHOLDS

Possible sources of information

WHO will pre-populate this table with household survey results and household access, if available. If you are aware of any reports containing similar data obtained using a different method, please attach a copy to your completed questionnaire and provide the URL if available.

Glossary

WTO AGREEMENT ON ASPECTS OF INTELLECTUAL PROPERTY RIGHTS WHICH AFFECT TRADE (TRIPS)

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) seeks to strike a balance between, on the one hand, the long-term social objective and which is to provide incentives for future inventions and creations and, on the other hand, the short-term objective which is to enable the public to use existing inventions and creations. The Agreement covers a wide range of topics, from copyright and trademarks to integrated circuit layout designs and trade secrets.
Patents protecting pharmaceuticals and other products are only part of the Agreement.

Balance works in three ways:

• Invention and creativity in themselves should bring social and technological benefits.

Intellectual property protection encourages inventors and creators because they can expect their creativity to provide them with certain future benefits. This encourages new inventions, such as new drugs, whose development costs can sometimes be extremely high, which is why private rights are also the source of social benefits.

• The way in which intellectual property is protected can also serve social objectives.
For example, patented inventions must be disclosed, allowing third parties to study them even while they are protected by a patent. This contributes to technological progress and the dissemination and transfer of technology. After a certain period, the protection ceases, which means that the invention becomes usable by third parties. All this avoids
to "reinvent the wheel".

• The TRIPS Agreement provides flexibility for governments to adjust the protection provided to achieve social goals. With regard to patents, they allow governments to make exceptions to the rights of patent holders such as in situations of national emergency, in the face of anti-competitive practices, or in the event that the right holder does not communicate the invention, provided certain conditions are met. As far as pharmaceutical patents are concerned, the flexibility granted has been clarified and reinforced by the 2001 Doha Declaration on TRIPS and public health.
This will to strengthen was concretized in 2003 with the adoption of a decision allowing countries which could not manufacture medicines themselves to import

pharmaceutical products manufactured under compulsory license. In 2005, Members agreed to make this decision a permanent amendment to the Agreement, which will take effect when two-thirds of Members accept it.

[See WTO Fact Sheet: TRIPS and Pharmaceutical Patents, *available at: http://www.wto.org/french/tratop_e/trips_e/factsheet_pharm00_e.html]*

ACCREDITATION

Accreditation is an evaluation process in which the policies, procedures and results of a healthcare organization are reviewed by an external body (accreditation body) to ensure that it meets predefined standards.

In the case of a healthcare facility, accreditation standards generally take into account the layout of the facility, its governing bodies, administration, and medical and non-medical staff. Accreditation is often issued by bodies specially created to assure the public of the quality of the institutions or programs concerned.

The State may recognize accreditation in lieu of certification, or use it as the basis for issuing the latter.

Public or private payment programs often require accreditation, which then becomes a condition of service funding.

Accreditation can be granted on a permanent basis or for a specific period.

[See "accreditation" in PHIS Glossary 2009 *at: http://phis.goeg.at/index.aspx?alias=phisglossary]*

SHOPPING

Process by which an entity procures products. The term covers the purchase itself, but also, by extension, donations and production.

[See Managing Drug Supply Second Edition, *Chapter 13, page 182,* Management Sciences for Health, *1997]*

The fact of obtaining, by purchase or otherwise, pharmaceutical products, vaccines or nutraceuticals for human use.

[See Model quality assurance system within purchasing centres, *WHO, Geneva, 2007.*
Available at: http:// apps.who.int/ medicinedocs/ documents/ s17075f/ s17075f.pdf]

“The process of buying drugs has many steps. Regardless of the model used to manage the procurement and distribution system, effective procedures must be in place:

- to select the most cost-effective essential drugs to treat diseases common;

- to quantify needs;

- to carry out a pre-selection of potential suppliers;

- to manage purchases and supplies;

- to ensure good product quality; and

- to monitor supplier and procurement system performance.

Failure in any of these areas leads to limitations in access to medicines appropriate and wasteful. »

[See Model quality assurance system within purchasing centres, *WHO, Geneva, 2007.*
Available at: http:// apps.who.int/ medicinedocs/ documents/ s14866e/ s14866e.pdf]

CALL FOR TENDERS

The procedure for purchasing pharmaceutical products consisting of soliciting, through a public announcement, price offers from suppliers.

It thus puts them in competition with a view to obtaining the lowest price. Tenders must be provided in a standardized format allowing comparisons to be made and thereby ensuring fair competition.

[See Model quality assurance system within purchasing centres, *WHO, Geneva, 2007. Available at: http:// apps.who.int/ medicinedocs/ documents/ s17075f/ s17075f.pdf]*

QUALITY ASSURANCE

Quality assurance is a broad concept covering all areas which separately or collectively influence the quality of a product. It is the set of operations carried out with the aim of ensuring that pharmaceutical products are of the quality required for their intended use.

[See Model quality assurance system within purchasing centres, *WHO, Geneva, 2007. Available at: http:// apps.who.int/ medicinedocs/ documents/ s17075f/ s17075f.pdf]*

HEALTH INSURANCE (HEALTH INSURANCE)

The term health insurance refers to all private or public health insurance programs, including for-profit or non-profit programs or organizations, and in particular those that include the poorest. Health insurance programs help to share financial risks between different populations. They support all or part of the health expenses of their members through contributions from individuals, employers, non-governmental organizations and/or governments.

[See: Prescribing Cultures and Pharmaceutical Policy in the Asia-Pacific 2009, edited *by Karen Eggleston and Walter H. Shorenstein, Asia-Pacific Research Center Books, and in particular Chapter 18 by Anita Wagner and Dennis Ross-Degnan: "Insurance Systems in the Asia-Pacific Region: Improving Appropriate Use of and Access to Medicines"]*

AUDIT

Auditing is an independent and objective activity designed to add value to an organization, improve its activities and help it achieve its objectives through a systematic and disciplined approach to evaluate and improve the effectiveness of risk management processes, control and governance.

[See WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 *at http:// infocollections.org/ medregpack/ interface/ files/ glossary.pdf]*

MARKETING AUTHORIZATION (HOMOLOGATION)

Legal document drawn up by the competent medicines control authority for the marketing or free distribution of a product whose safety, efficacy and quality have been assessed. This document must specify, among other things, the name of the product, its galenic form, its quantitative composition (including excipients) per dose (using the INNs or the national generic names when they exist), the shelf life and the storage conditions and, finally, the characteristics of the packaging. It specifies the information on which the authorization is based (it specifies, for example, that the product in question must comply with all the details provided in the application and as amended in subsequent correspondence). It also contains approved information for healthcare professionals and the public, the type of sale (prescription or over-the-counter), the name and address of the authorization holder, and the validity period of the authorization. . When marketing authorization for a product has been given, it is placed on a list of authorized products – and it is often said to be “approved”. Marketing authorization is also sometimes called a “licence”.

[See Model quality assurance system within purchasing centres, *WHO, Geneva, 2007. Available online at : http:// apps.who.int/ medicinedocs/ documents/ s17075f/ s17075f.pdf]*

PHARMACEUTICAL REGULATORY AUTHORITY

A national authority with the *legal mandate to define the objectives of all pharmaceutical regulatory activities and to administer those activities,* including performing at least one of the following functions, in accordance with national pharmaceutical legislation:

- marketing authorization for new products and variations of existing products;

- quality control of laboratory examinations;

- monitoring of adverse drug reactions;

- provision of information on medicines and promotion of their rational use;

- Good Manufacturing Practices (GMP) inspections and certification of manufacturers, wholesalers and distributors;

- activities related to the repression of offences;

- monitoring of drug use.

[Adapted from WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014, *available at http:// infocollections.org/ medregpack/ interface/ files/ glossary.pdf]*

ADVERSE DRUG EFFECTS DATABASE

An adverse drug reaction database is a management system for monitoring occurrences of adverse drug reactions and their evolution. The WHO Collaborating Center for Pharmacovigilance maintains a global database called *Vigibase* in which adverse drug reactions are listed.

GOOD GOVERNANCE IN PHARMACEUTICAL PRACTICES

The Good Governance in Pharmaceutical Practices program was launched at the end of 2004 by the World Health Organization (WHO) as part of its 2004-2007 pharmaceutical strategy. Its objective is to curb corruption in the pharmaceutical sector through the application of transparent administrative procedures for which healthcare professionals are accountable and the promotion of ethical practices. In this way, WHO aims to help countries maintain effective health care systems.

[See: WHO Good Governance for Medicines Progress Report, WHO, Geneva, 2009, at : http:// apps.who.int/ medicinedocs/ documents/ s16218e/ s16218e.pdf]

GOOD CLINICAL PRACTICE (GCP)

Standard for the design, conduct, effectiveness, monitoring and verification of clinical trials and the recording, analysis and presentation of data relating thereto and which guarantees the reliability and accuracy of the data and the results presented as well as the protection of the rights, integrity and identity of the subjects. [Source: ICH Guidelines on Good Clinical Practice]

[See "good clinical practice" in PHIS Glossary 2009 *at : http:// phis.goeg.at/ index.aspx? alias=phisglossary]*

GOOD DISTRIBUTION PRACTICE (GDP)

As part of quality assurance, ensures that the quality of pharmaceutical products is maintained throughout the many stages of the distribution process. A well-managed distribution system achieves the following objectives: maintaining a constant supply of drugs, keeping drugs in good condition throughout the distribution process, minimizing drug losses due to wastage and expiration, keep accurate inventory records, store drugs rationally, use available means of transportation as efficiently as possible, reduce theft and fraud, and provide information to forecast drug needs.

[See Model Quality Assurance System Within Central Procurement Organizations, WHO, Geneva, 2007, at: http:// apps.who.int/ medicinedocs/ documents/ s17075e/ s17075e.pdf]

GOOD MANUFACTURING PRACTICE (GMP)

Quality assurance factor that guarantees that medicines are always produced and controlled in accordance with the quality standards appropriate to their destination and
in accordance with the conditions of the marketing authorisation.

[See Model Quality Assurance System Within Central Procurement *Organizations, WHO, Geneva, 2007, at: http:// apps.who.int/ medicinedocs/ documents/ s17075e/ s17075e.pdf]*

GOOD PHARMACEUTICAL PRACTICE (GPP)

The practice of offering patients and the public the best possible use of medicines, products and other health care services and of promoting such use. The well-being of the patient must therefore be a permanent priority for the pharmacist.

[See " good pharmacy practice" in WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 *at http:// infocollections.org/ medregpack/ interface/ files/ glossary.pdf]*

PATENT

Patents offer their owners the legal means to prevent third parties from making, using or selling the new invention for a limited period, subject to a number of exceptions.

A patent is not an authorization to put a product on the market. A patent only gives an inventor the right to prevent others from using the patented invention. It gives no indication as to whether the product is safe for the consumer and whether it can be supplied. Patented pharmaceuticals still need to be rigorously tested and approved before they can be marketed.

[See WTO Fact Sheet: TRIPS and Pharmaceutical Patents, available at: http://www.wto.org/french/tratop_e/trips_e/factsheet_pharm00_e.html]

HEALTH FUND

A sickness fund is a health insurance institution. In some countries, several health insurers coexist or even compete. Some sickness funds operate on a regional scale, while others target specific professional categories (farmers or self-employed, for example).

[See 'sickness fund' in PHIS Glossary 2009 at http://phis.goeg.at/index.aspx?alias=phisglossary]

REIMBURSEMENT CATEGORY (REIMBURSEMENT GROUP)

Reimbursable medicines are often grouped according to their characteristics, eg route of administration (oral, etc.), main indication (oncology, paediatrics), ATC level, classification (medicine for hospital use). In many countries, different reimbursement rates apply to these different categories.

[See 'reimbursement category' in PHIS Glossary 2009 at http://phis.goeg.at/index.aspx?alias=phisglossary]

PURCHASING CENTRAL (PURCHASING ORGANIZATION)

A purchasing group ÿ or purchasing organization ÿ designates any organization that purchases, or obtains by other means, pharmaceutical products, vaccines, or nutraceuticals for human use.

[See Model quality assurance system within purchasing centres, WHO, Geneva, 2007. Available at: http://apps.who.int/medicinedocs/documents/s17075f/s17075f.pdf]

NATIONAL PHARMACOVIGILANCE CENTER

Organization recognized by the government as being able to represent its country in the WHO program (usually the drug regulatory agency). It is a single center (or coordinated system) recognized by the public authorities and having the clinical and scientific expertise necessary to collect, collate and analyze all information relating to the safety of medicinal products as well as to give advice about them.

[See definition of "national pharmacovigilance center" at: http:// www.who umc.org/ DynPage.aspx? id=13111&mn=1513]

PHARMACEUTICAL PRODUCT CERTIFICATE

WHO Model Certificate as defined in the Guidelines for the Application of the WHO Certification Scheme on the Quality of Pharmaceutical Substances in Commerce international.

[See WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 *at http:// infocollections.org/ medregpack/ interface/ files/ glossary.pdf]*

CODE OF CONDUCT

A code of conduct is a set of binding principles and rules to which everyone belonging to a given group is bound.

[Available at http:// wordnet.princeton.edu/]

ETHICS COMMITTEE (EC); ESTABLISHMENT EVALUATION COMMITTEE (CEE)

The ethics committee ensures that biomedical research adheres to international guidelines including the Declaration of Helsinki, the International Guidelines on the Ethical Aspects of Biomedical Research Involving Human Subjects (CIOMS) and the Guidelines of the ICIDH and the Guidelines on Good Clinical Practice (GCP). The role of an EC in reviewing biomedical research is to help safeguard the dignity, rights, safety, and well-being of all current and potential research participants. A cardinal principle of research involving human subjects is "respect for the dignity of the person". While important, research objectives do not

must never put the health, well-being and care of research participants in the background. The EC must also consider the principle of justice. This principle requires that the benefits and harms of research be distributed equitably among all groups and classes of society, taking into account age, gender, economic status, culture and ethnic considerations. ECs must carry out an independent, competent and diligent ethical review of proposed research. In their composition, their procedures and their mode of decision-making, the Works Councils must be independent of all political, institutional, professional and economic influences. They must also demonstrate competence and efficiency in their work. ECs are responsible for reviewing proposed research prior to implementation. They must also ensure that ongoing research which has received a favorable opinion is regularly reassessed from an ethical point of view. ECs are required to act in the full interest of potential research participants and affected communities, taking into account the interests and needs of researchers and giving due consideration to the requirements of relevant regulatory bodies as well as to the legislation in force.

[See definition of "ethics committee" in Operational guidelines for ethics committees responsible for the review of biomedical research, *WHO, Geneva, 2000, at: http:// apps.who .int/ tdr/ publications/ training-guideline-publications/ operational -guidelines-ethics-biomedical-research/ pdf/ ethicsfr.pdf]*

PHARMACEUTICAL AND THERAPEUTIC COMMITTEE (CPT)

A pharmaceutical and therapeutic committee is a group of people recognized and officially approved by the Ministry of Health and/or by the management of a health establishment. He promotes the safe and effective use of medicines in the region or institution under his jurisdiction.

[See definition in Drug and therapeutics committees, a practical guide, *WHO, Geneva, 2003, at:* http:// apps.who.int/medicinedocs/en/d/Js4882e/3.html]

INTERNATIONAL CONFERENCE ON HARMONIZATION OF TECHNICAL REQUIREMENTS RELATING TO THE APPROVAL OF PHARMACEUTICAL PRODUCTS FOR HUMAN USE (CIH)

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together regulatory bodies from Europe, Japan and the United States as well as experts of the pharmaceutical industry from the three regions to discuss the scientific and technical aspects of product registration.

The aim is to make recommendations on how to have greater harmonization in the interpretation and application of the guides and criteria for product registration in order to reduce or eliminate the need for duplication of tests carried out during research and development of new drugs.

The objective of such harmonization is a more economical use of human beings, animals and material resources but also the elimination of unnecessary delays in the development and availability of new medicines while maintaining safeguards for quality, safety and efficacy as well as regulatory obligations to protect public health.

[See http:// www.ich.org/ cache/ compo/ 276-254-1.html]

CONFLICT OF INTEREST

Situation in which the decisions of a public representative are influenced by his own interests.

[Definition of "conflict of interest" at http:// wordnet.princeton.edu/]

This term is generally defined as a conflict between an individual's private or personal interests and their duties. It can, however, refer to a situation where an individual exercises several functions that are incompatible without his private or personal interests being at stake. Resolving a conflict of interest means putting an end to any distortion which, in the decision-making process , is the subject of a reasonable or irrebuttable presumption.

[Adapted from the Pan American Health Organization Governance Manual]

OPIOID USE

The amount of opioids/painkillers legally distributed in a country for medical purposes to institutions and programs authorized to dispense them to patients, such as hospitals, nursing homes, pharmacies, hospices, and palliative care programs. In the context of international drug control, the term “consumption” does not refer to quantities dispensed or consumed by patients, but rather quantities sold at retail.

[See “consumption of opioids” at http:// www.painpolicy.wisc.edu/ glossary.htm]

QUALITY CONTROL

The part of Good Manufacturing Practices (GMP) that concerns sampling, specifications and testing. It also concerns the documentation and the acceptance/rejection procedures by the purchasing group, which guarantee that the necessary and relevant tests are actually carried out and that the use, sale or supply of raw materials, intermediate products and finished products are not permitted until their quality has been determined to be satisfactory. Quality control is not limited to laboratory activities but must be involved in all decisions relating to product quality.

[See WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014, *available at http:// infocollections.org/ medregpack/ interface/ files/ glossary.pdf]*

1971 CONVENTION ON PSYCHOTROPIC SUBSTANCES

This convention establishes an international control system for psychotropic substances. Its creation aimed to respond to the diversification and development of different types of drug addiction. It establishes controls on several synthetic drugs according to the risk of abuse attached to them and their therapeutic effect.

[See http:// www.incb.org/ incb/ convention_1971.html]

UNITED NATIONS CONVENTION AGAINST ILLICIT TRAFFIC IN NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES (1988)

This international convention proposes general measures against drug trafficking, in particular provisions against money laundering and the diversion of chemical precursors. It promotes international cooperation, notably through the extradition of drug traffickers, controlled deliveries and the transfer of criminal proceedings.

[See http:// www.incb.org/ incb/ convention_1988.html]

SINGLE CONVENTION ON NARCOTIC DRUGS (1961)

The adoption of this international treaty is considered a milestone in the history of international drug control. The Single Convention codified all existing multilateral drug control treaties and extended the scope of existing control systems to the cultivation of plants used as raw materials for narcotics. It aims first of all to limit exclusively to medical and scientific uses the possession, consumption, trade, distribution, import, export, manufacture and production of drugs, and to fight against drug trafficking through international collaboration to deter and discourage traffickers. The Convention also created the International Narcotics Control Board, resulting from the merger of the Permanent Central Committee and the Supervisory Committee.

[See: http:// www.incb.org/ incb/ en/ convention_1961.html]

COST, INSURANCE AND FREIGHT (CIF)

Maritime term meaning that the seller must pay the costs and charges of insurance and freight necessary to bring the goods to the port of arrival.

[See Measuring Medicine Prices, Availability, Affordability, and Price Components *(HAI-WHO), available at http:// www.haiweb.org/ medicineprices/ manual/ documents.html]*

MEDICATION COVERAGE (PHARMACEUTICAL BENEFITS)

Drug coverage refers to the pharmaceutical benefits provided by health insurance to its beneficiaries. It can be complete, when all drug costs are reimbursed, or partial, if the insurance pays or reimburses only part of the cost of drugs or if it excludes some of them.

SOCIAL HEALTH COVERAGE

Social health coverage makes it possible to finance health care through contributions from employers and employees and through state subsidies. In many countries, compulsory schemes apply to employees whose income does not exceed a certain threshold – this is called "compulsory insurance". Social health coverage often includes several health insurance funds. In some countries (Germany, for example), the patient can choose between them, while in others membership of a fund is determined by the type of job held (notably in Poland or Austria). People with the highest incomes and the self-employed can also sometimes opt for private health insurance replacing the public system. There are also voluntary health insurance schemes that allow you to cover co-payments or choose your doctor. They are often very popular.

[See "social health insurance" in PHIS Glossary 2009 *at http://phis.goeg.at/index.aspx?alias=phisglossary]*

DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

In the main Doha Ministerial Declaration of 14 November 2001, governments WTO members stressed the importance of implementing and interpreting the TRIPS Agreement in a way that promotes public health, including by promoting access to existing drugs and the creation of new drugs.

They therefore adopted a separate declaration on TRIPS and public health. They agreed that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. They stressed the possibility for Members to exploit the flexibilities provided for in the TRIPS Agreement, including compulsory licensing and parallel imports. They also agreed to extend until 2016 the exemptions granted to the least developed countries with regard to the protection conferred by a patent on pharmaceutical products.

On an outstanding issue, they instructed the TRIPS Council to carry out further work - to find out how to provide additional flexibility that would allow countries that are unable to manufacture pharmaceuticals on their territory to obtain other countries copies of patented medicines. (This issue is sometimes referred to as "paragraph 6" because that is the paragraph of the separate statement on TRIPS and public health where it is addressed).

[See WTO Fact Sheet: TRIPS and Pharmaceutical Patents *at : http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf]*

INTERNATIONAL NON-OWNER NAME (INN)

A unique, globally recognized name that is in the public domain. From the outset, the objective of the INN system has been to enable healthcare professionals to recognize any pharmaceutical substance by means of a single universal name. The existence of an international nomenclature for pharmaceutical substances, in the form of INNs, is important: clear identification allows medicines to be prescribed and dispensed to patients in complete safety and facilitates communication and the exchange of information between health professionals and scientists around the world.

Unambiguous designations, INNs must be distinguished by their sound and their spelling and not cause confusion with other common designations. To guarantee their universality, the WHO has officially placed INNs in the public domain, hence their designation as “common”. They can be used without restriction to designate pharmaceutical substances.

An important feature of the INN system is that the name of each substance must indicate its pharmacological relationship by means of a common "key segment". The use of these key segments allows physicians, pharmacists, or anyone dealing with pharmaceuticals to recognize that a substance belongs to a group of substances with similar pharmacological activity.

Nonproprietary names are intended for use in pharmacopoeias, labelling, product information, advertising and promotional material, pharmaceutical regulation and scientific literature, and as the basis for product names, for example for generic drugs. Their use is normally required by national law or, in the European Union, by Community law.

Thanks to the collaboration, the names of several national systems – British Approved Names (BAN), French Common Names (DCF), Japanese Adopted Names (JAN) and United States Adopted Names (USAN) – are today, with rare exceptions nearly identical to INNs.

To avoid confusion, which could endanger patient safety, a mark should not be derived from an INN and, in particular, should not incorporate a key segment
common.

[See WHO INN guidance at : http:// www.who.int/ medicines/ services/ inn/ innguidance/ en/ index.html]

HEALTH EXPENDITURE (TOTAL HEALTH EXPENDITURE)

Health expenditure is defined as the sum of expenditure devoted to activities which, through medical, paramedical and nursing knowledge and techniques, aim to:

- promote health and prevent disease;

- cure diseases and reduce premature mortality;

- taking care of the chronically ill requiring nursing care;

- take care of people with impairments, disabilities or handicaps requiring nursing care;

- help patients die with dignity;

- design and implement public health actions;

- design and manage health programs, health insurance mechanisms and other funding mechanisms.

Health expenditure includes expenditure on:

- **individual health** (curative care, rehabilitation care, long-term nursing care, auxiliary health care services, delivery of medical products to non-hospitalized patients), and

- **collective health** (prevention and public health, administration and insurance).

Health expenses can be:

- public: financing by national, regional and local public bodies and by social security systems.

- private: financing by the private sector. Private sources of funding include out-of-pocket payments (both co-payments and over-the-counter payments), private insurance programs, charities, and community medical services.

work.

[See "health expenditure" in PHIS Glossary 2009 *at http://phis.goeg.at/ index.aspx?alias=phisglossary]*

PRIVATE HEALTH SPENDING

The total share of health expenditure financed by the private sector. Private sources of funding include out-of-pocket payments (both co-payments and over-the-counter payments), private insurance programs, charities, and occupational health services.

In contrast, public health expenditure is financed by national, regional and local public bodies and by social security systems.

[See "private health expenditure" in PHIS Glossary 2009 *at http:// phis.goeg.at/ index.aspx?alias=phisglossary]*

PUBLIC HEALTH EXPENDITURE

Health expenditure financed by national, regional and local public bodies and by social security systems.

Private expenditure is the total share of expenditure financed by the private sector.
Private sources of funding include out-of-pocket payments (both co-payments and over-the-counter payments), private insurance programs, charities, and occupational health services.

[See "government health expenditure" in PHIS Glossary 2009 *at: http:// phis.goeg.at/ index.aspx?alias=phisglossary]*

WHOLESALE DISTRIBUTION

Any activity which consists of procuring, holding, supplying or exporting medicinal products, excluding their supply to the public.

These activities are carried out with manufacturers or their agents, importers, other wholesalers or with pharmacists and persons authorized or empowered, in the Member State concerned, to supply medicinal products to the public.

Wholesalers have a public service obligation: they are required to permanently guarantee a range of medicinal products capable of meeting the requirements of a geographically determined territory and to ensure the delivery of the supplies requested within very short deadlines throughout the said territory. territory.

[Source: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 establishing a Community code relating to medicinal products for human use]

[See "wholesale" in PHIS Glossary 2009 *at http:// phis.goeg.at/ index.aspx?alias=phisglossary]*

DISTRIBUTER

A company (eg, pharmacy or other outlet) that sells products to consumers. In low- and middle-income countries, at least two different types of medicine outlets often coexist: actual pharmacies, managed by registered pharmacists, and pharmacies or stores where medicines are dispensed by paramedical staff or not. qualified.

DISTRIBUTION

Distribution and transport of pharmaceutical products from the premises of the manufacturer or another central point, to the final consumer, or to an intermediate place by means of different modes of transport, via different storage and/or health establishments.

[See WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 *at* http://infocollections.org/medregpack/interface/files/glossary.pdf]

IMPORT DUTY (IMPORT CUSTOMS DUTY)

An import duty may apply to all imported medicines, but there may be a system in place to exempt certain products or purchases. The import tax or duty may or may not apply to raw materials for local production.
This varies by product.

[See HAI-WHO, Measuring Medicine Prices, Availability, Affordability, and Price Components *(Second Edition), http:// www.haiweb.org/ medicineprices/ manual/ documents.html]*

SAMPLE

A portion of material collected under a defined procedure. The size of the samples must be sufficient so that all the test procedures foreseen are carried out, and in particular so that they can be repeated and that certain samples are retained. If the quantity of material available does not allow the necessary studies to be carried out and certain samples to be kept, the inspector must indicate that these have been made up on the basis of the material available; it will therefore be necessary to take into account, in the evaluation of the results, the limits inherent in an insufficient sample size.

[See WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014, available at *http:// infocollections.org/ medregpack/ interface/ files/ glossary.pdf]*

SAMPLING

Operation aimed at obtaining a representative portion of a pharmaceutical product, on the basis of an appropriate statistical procedure and for a particular reason (for example, acceptance or release of batches). (See sample).

[See WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014, available at http:// infocollections.org/ medregpack/ interface/ files/ glossary.pdf]

ADVERSE REACTION (SIDE EFFECT OF A MEDICATION)

Adverse and unwanted reaction to a drug, occurring at dosages normally used in man for the prophylaxis, diagnosis or treatment of disease or for the restoration, rectification or modification of physiological function (WHO, 1972).

An adverse drug reaction, unlike an adverse event, is characterized by a presumed causal link between the drug and the occurrence, i.e. the reporting physician has judged such a link to be possible.

[See http://www.who-umc.org/DynPage.aspx?id=13111&mn=1513]

Serious adverse reaction: adverse reaction resulting in death or endangering the life of the patient, provoking or prolonging hospitalization, leading to significant or long-lasting handicap or incapacity, or resulting in a congenital anomaly/malformation.

Unexpected adverse reaction : an adverse reaction whose nature, severity or outcome is not consistent with the summary of medicinal product characteristics.

[Source: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 establishing a Community code relating to medicinal products for human use]

[See "adverse reaction" in PHIS Glossary 2009 *at : http:// phis.goeg.at/ index.aspx?alias=phisglossary]*

WHO LEVEL II FACILITY SURVEY

Level II health facility indicators provide data
to measure the results obtained in terms of access – affordability and availability of the main medicines – and the rational use of quality medicines, and in particular to obtain indications on the quality of the medicines available in the establishments health and pharmacies. This information is collected through systematic surveys in countries of public health facilities, public and private pharmacies and public warehouses. The results of these surveys make it possible, if necessary, to assess the extent to which the objectives set by the pharmaceutical sector have been achieved (in particular with regard to the national pharmaceutical policy).

The results also show which areas require particular attention and which strategies should be implemented in priority in the different establishments, districts and countries.

[See: WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situations: Guide for coordinators and data collectors, WHO, Geneva, 2007, available at: http:// apps.who.int/ medicinedocs/ documents/ s14877e / s14877e.pdf]

MEDICATION ERROR

A medication error refers to any avoidable event occurring during medication management by the healthcare professional, the patient or the consumer, likely to lead to inappropriate use of the medication or to be harmful to the patient.
These events may be related to professional practice; healthcare products, procedures and systems, including prescription; when placing orders; labelling, packaging and nomenclature; the preparation of drugs, their dispensing, their administration and their distribution; indications for use; monitoring and use itself.

[See: http:// www.nccmerp.org/ aboutMedErrors.html]

LIFE EXPECTANCY AT BIRTH

Estimated number of years a male or female infant will live, based on age-specific mortality rates. Life expectancy at birth by sex gives a statistical summary of the differences observed between male and female mortality, in all age groups. In areas where infant and child mortality rates are high, trends and mortality differences between these two categories weigh heavily on the indicator.

[See "life expectancy at birth" at http://
unstats.un.org/ unsd/ demographic/ products/ socind/ health.htm#tech]

CLINICAL TRIAL (CLINICAL STUDY)

Systematic study of a drug in human subjects (including patients and other volunteers) with a view to discovering or verifying its effects, recognizing possible adverse reactions and/or studying the absorption of the product in question, its distribution, metabolism and excretion in order to assess its efficacy and safety.

There are generally four phases in clinical trials (phases I to IV). It is not possible to draw a clear boundary between each phase and opinions differ as to details and methodology.

Below is a brief description of each phase based on the objective pursued, seen from the perspective of the clinical development of drugs.

Phase I. First human trials of a new active ingredient or a new formulation. These trials are usually performed on healthy volunteers. Their objective is to allow a preliminary evaluation of the safety as well as the pharmacokinetic profile, and if possible pharmacodynamic profile, of the active ingredient in humans.

Stage II. The objective of these pilot therapeutic studies is to determine the activity and to evaluate the short-term safety of the active substance in patients suffering from a disease or condition for which the product was intended. Phase II trials are performed on a limited number of subjects; when they reach a more advanced stage, they are often comparative in nature (for example, compared to a placebo). This phase also aims to determine the appropriate dose range or posology and (if possible) to establish the dose-response relationship, so as to provide an optimal basis for the design of large-scale therapeutic trials.

Phase III. Phase III trials involve larger (and possibly heterogeneous) groups of patients to determine the relationship between the short- and long-term safety and efficacy of the active ingredient formulation(s), and to assess their overall and relative therapeutic interest. If the product gives rise to frequent adverse reactions, their profile must be studied, as well as certain special characteristics of the product (clinically significant drug interactions, factors such as age which may affect efficacy, etc.). Trials should preferably be randomized and double-blind, but other types of studies may be acceptable, for example long-term safety studies. As a general rule, the conditions under which the test is conducted should be as close as possible to normal conditions of use.

Stage IV. Phase IV trials are done after the drug has been marketed. They are carried out according to the characteristics of the product which motivated the marketing authorization. They generally take the form of pharmacovigilance studies, or an assessment of therapeutic benefit or treatment strategies. Although the methods used may be different, these studies must be based on the same scientific and ethical standards as premarketing studies. Once a product has been released to market, clinical trials that aim to investigate new indications for the product, new methods of administration or new combinations, etc. are generally considered studies of new pharmaceuticals.

[See WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 *at http:// infocollections.org/ medregpack/ interface/ files/ glossary.pdf]*

POST-MARKETING SURVEILLANCE STUDY

A post-marketing surveillance study is generally synonymous with a phase IV study (see clinical trial). These studies are carried out according to the characteristics of the product which motivated the marketing authorization. They generally take the form of pharmacovigilance studies, or an assessment of the therapeutic benefit or treatment strategies. Although the methods used may be different, these studies must be based on the same scientific and ethical standards as premarketing studies. When a product has been placed on the market, clinical trials relating to the search for new indications, new methods of administration, new combinations, etc. are normally considered to be trials of new products.

[Adapted from WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014, *available at http:// infocollections.org/ medregpack/ interface/ files/ glossary.pdf]*

EXCEPTION FOR THE “BOLAR” PROVISION

Many countries use the TRIPS Agreement to advance science and technology. They allow researchers to use a patented invention for research purposes, to better understand the invention.

In addition, some countries allow generic drug manufacturers to use the patented invention to obtain marketing approval—for example, from public health authorities—without the patent holder's permission and before the patent protection does not expire. Generic drug producers can then market their products as soon as the patent expires. This provision is sometimes referred to as the “regulatory exception” or the “Bolar” provision. *Article*

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This point was confirmed in a ruling in a WTO dispute as being in accordance with the TRIPS Agreement. In its report adopted on April 7, 2000, a WTO dispute settlement panel said Canadian law complied with the TRIPS Agreement by allowing manufacturers to do so . (The case is entitled "Canada — Patent Protection for Pharmaceutical Products".)

[See the WTO Fact Sheet: TRIPS and Pharmaceutical Patents at : http://www.wto.org/french/tratop_e/trips_e/factsheet_pharm02_e.htm#bolar]

DATA EXCLUSIVE

A form of protection for the original data of a pharmaceutical company aimed at preventing its commercial use by third parties. In concrete terms, this protection prevents manufacturers of generic products from carrying out clinical trials, and health authorities from examining, for a given period, requests for marketing authorization for generic products. In 2004, this period was harmonized at eight years in the European Union.

[See OECD – Medicine Prices in a Global Market, *at: http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html]*

OPERATOR

Any natural or legal person responsible for information, advertising and pharmacovigilance concerning a pharmaceutical product, as well as the monitoring of batches and, if necessary, their withdrawal, whether or not they hold marketing authorization.

[See WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at *http:// infocollections.org/ medregpack/ interface/ files/ glossary pdf]*

MAKER

A manufacturer is a natural or legal person responsible for manufacturing a product.

[See "manufacturer" in PHIS Glossary 2009 , *available at http:// phis.goeg.at/ index.aspx?alias=phisglossary]*

A local manufacturer is an entity headquartered in the country.

MANUFACTURING

Manufacturing includes, for active pharmaceutical ingredients, all operations relating to the receipt of raw materials, production, packaging, repackaging, labelling, relabelling, quality control, putting into circulation, storage and distribution, as well as the related checks.

[See "manufacturing" in PHIS Glossary 2009 , *available at http:// phis.goeg.at/ index.aspx?alias=phisglossary]*

DOSAGE FORM (PHARMACEUTICAL FORM)

The technical pharmaceutical form in which an active substance is offered. Pharmaceutical products can be administered in solid (tablets, powders, etc.), semi-solid (ointments, pastes, etc.), liquid (drops, solutions for injection, infusions, etc.) or pressurized (inhalation) form.

[See OECD – Medicine Prices in a Global Market, at: *http:// www.oecd.org/ document/ 36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html]*

FORM

A formulary is a manual containing a clinical summary of pharmacological information about certain drugs. The manual may also include administrative and regulatory information relating to the prescription and dispensing of drugs.

A national formulary generally covers available and affordable medicines useful for the treatment of diseases in a given country. Forms are also often created to cover different levels of care, different sectors and hospitals.

[See How to develop a national formulary based on the WHO model formulary, a practical guide, WHO, Geneva, 2004, at: http:// apps.who.int/ medicinedocs/ en/ d/ Js6171e/ 2.3. html]

GENERIC

Pharmaceutical product which has the same qualitative and quantitative composition of active substances and the same pharmaceutical form and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.

The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance are considered to be one and the same active substance, unless they have significantly different properties in terms of safety and/or or efficiency. The depositor/applicant must provide additional information guaranteeing the harmlessness and/or the effectiveness of the various salts, esters or derivatives of an authorized active substance.

The different immediate-release oral pharmaceutical forms should be considered as one and the same pharmaceutical form.

Generics can be classified as either branded generics (with a specific brand name) or unbranded generics (they use the international nonproprietary name and the name of the laboratory). [Source: European Parliament Directive 2001/83/EC
and of the Council of 6 November 2001 instituting a Community code relating to medicinal products
human use]

[See "generic" in PHIS Glossary 2009 at : http:// phis.goeg.at/ index.aspx?alias=phisglossary]

STANDARDIZED TREATMENT GUIDES (GTN)

Standard treatment guidelines briefly outline recommended – ie consensus – treatments for common conditions. The purpose of these guides is to standardize treatments on the scale of a health system and to rationalize the prescription for the conditions covered.

The widespread adoption and application of standardized treatments also allows them to be used to quantify drug needs, together with morbidity and attendance data. The GTNs are, moreover, useful to prescribers. They constitute for them reference texts in their daily clinical work and are also used for initial and continuing training.

[See "standard treatment guidelines" in Producing national drug and therapeutic information: The Malawi approach to developing standard treatment guidelines Geneva 1999, *document available at: http:// apps.who.int/ medicinedocs/ pdf/ whozip24e/ whozip24e .pdf]*

FEES ON PHARMACEUTICAL ACTS

This is usually a fixed amount per prescribed item that pharmacies are entitled to charge, instead of or in addition to their markup. The fee more accurately reflects the work involved in processing the prescription; a percentage profit margin makes the profit dependent on the sale of high priced drugs.

[See "dispensing fee" in PHIS Glossary 2009 *at : http:// phis.goeg.at/ index.aspx?alias=phisglossary]*

HOSPITAL

A licensed facility primarily responsible for providing inpatient medical, diagnostic and treatment services, including physician and nursing services and other health care and specialized accommodation. Hospitals offer specialized care that can only be delivered through fully integrated specialized equipment and devices. In some countries, to qualify as hospitals, health facilities must meet size criteria (eg number of beds).

Hospitals sometimes offer additional outpatient services.

They can be classified into three categories: general hospitals, psychiatric hospitals and establishments for drug addicts and other specialized centres.

A **general hospital** is an approved facility primarily responsible for diagnosing and providing treatment (including surgery) to hospitalized patients with a wide variety of conditions. Other services are sometimes offered: outpatient consultations, anatomo-pathology, radiography, clinical laboratories, various operating services and pharmacy services.

Psychiatric **hospitals and addiction** facilities are licensed facilities primarily responsible for diagnosing, providing medical treatment, and monitoring inpatients with mental illnesses or addictions. Treatment usually requires fairly long stays; establishments are therefore equipped to house and feed patients. They offer psychiatric, psychological and social assistance services. In addition, there are usually outpatient centers, clinical trial laboratories, and X-ray and electroencephalography services.

A **specialty hospital** is a licensed facility primarily responsible for diagnosing and providing medical treatment to inpatients with a particular illness or condition (other than mental illnesses or addictions). Included in this category are hospitals that provide long-term care for the chronically ill and those that provide rehabilitation and related services to people with disabilities. These facilities sometimes offer outpatient clinics, x-ray services, clinical laboratories, surgical, physical therapy, educational and vocational services, as well as psychological and social work services.

[See "hospital" in PHIS Glossary 2009 *at : http:// phis.goeg.at/ index.aspx?alias=phisglossary]*

REFERRAL HOSPITAL

Referral hospitals are tertiary care centers. Their main function is to serve as a reference center for secondary care establishments (general hospitals), in all their specialties. In some cases, they can even provide secondary or even primary care. There are two main categories of referral hospitals:

- large hospitals, which provide a wide range of services, including specialty services,

- hospitals specializing in certain types of patients (children for example) or conditions (oncology for example).

GENERAL HOSPITAL

General hospitals are secondary care centers. They mainly serve as a referral center for primary care centers and offer a direct service to the population of their sector. They typically offer short-stay medical, surgical, pediatric, and obstetric services. They do not have all the specialized services (oncology, cardiology, neurosurgery, etc.) even if one or two services offering tertiary care are sometimes present.

IMPORTER

A natural person, or comparable business or legal entity, who imports or seeks to import a pharmaceutical product. An “approved” or “approved” importer has received an authorization or license for this purpose. In addition to the general import license, some countries require specific authorization to be issued by the national drug regulatory authority.

[See WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 *at http:// infocollections.org/ medregpack/ interface/ files/ glossary.pdf]*

PARALLEL IMPORTS

Parallel or “grey market” imports are not imports of counterfeit or illegally copied items. These are products marketed by the owner of the patent (or trademark or copyright, etc.) or with his authorization in one country and imported into another country without his approval.

[See National policy on traditional medicine and regulation of herbal medicines: report of a WHO global survey *and http:// apps.who.int/ medicinedocs/ en/ d/ Js7916e/ 3.html]*

INDICATOR

Parameter which aims, with the help of a few figures and in as much detail as possible, to describe a system, with a view to improving its understanding, establishing comparisons and forecasts, making improvements and innovate. Indicators perform two main functions: they reduce the number of criteria and parameters that would normally be needed to accurately describe a situation and facilitate the communication of results.

A distinction is generally made between structural, process and result indicators. The data used can be, depending on the case, quantitative or qualitative.

Structural indicators provide qualitative information to assess the ability of a pharmaceutical system to achieve its strategic objectives. They are used to verify whether the key structures/systems/mechanisms necessary for the implementation of a pharmaceutical policy exist in the country (eg dispensaries dispensing prescription drugs).

Process indicators are used to assess whether the activities necessary to achieve the objectives are carried out correctly and what their results have been over time (for example, pricing policy).

Outcome indicators are used to assess the results achieved and the changes attributable to a policy (eg life expectancy).

[See "indicator" in PHIS Glossary 2009 *at: http:// phis.goeg.at/ index.aspx?alias=phisglossary]*

MALE NURSE

A nurse is a person who has undergone basic training in the field, authorized as such to practice in his country in different ways. These healthcare professionals assist doctors in carrying out their duties, manage emergency situations in their absence, and provide nursing care to the sick, injured, physically or mentally disabled, and other people likely to need their services.

They may also perform deliveries or assist other professionals on this occasion, provide antenatal and post-natal care and advise parents on the care of infants.

[Source: EUROSTAT. “Definitions and data collection specifications on health care statistics (non-expenditure data)].

[See “nurse” in PHIS Glossary 2009 *at http://phis.goeg.at/index.aspx?alias=phisglossary]*

INFORMANT

An informant is a person who denounces a failure observed in an organization in the hope of putting an end to it.

[See definition of "whistle-blower" at http://wordnet.princeton.edu/]

REGULATORY INSPECTION

A formal review (including quality assurance procedures, personnel, any delegations of responsibility and audits) conducted by competent authorities at the locations where pharmaceutical activities take place (manufacturing, wholesale, testing , distribution and clinical trials) in order to monitor compliance with best practices.

[Adapted from WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014, *available at http://infocollections.org/medregpack/interface/files/glossary.pdf]*

LEGISLATION

First stage of the legislative process, during which the legislative body adopts laws relating to an area, for example the control of medicines. The laws define the roles, rights and obligations of all parties involved in this area in general (see also regulations below).

[See "legislation" in Model quality assurance system within central purchasing bodies, WHO, 2007, Geneva, at : http:// apps.who.int/ medicinedocs/ documents/ s14866e/ s14866e .pdf]

MANDATORY LICENSE

License granted by an administrative or judicial body to a third party for the exploitation of an invention without the consent of the patent holder. The expression "non-voluntary license" is also often found, which better reflects the absence of the consent of the holder.

[The part of the TRIPS Agreement dealing with compulsory licensing is found in Article 31. Retrieved from " Utilizing Trips Flexibilities for Public Health Protection through south-south Regional Frameworks *", South Centre, http:// apps.who.int/ medicinedocs/ en/ d/ Js4968e/ 1.html#Js4968e.1]*

REIMBURSEMENT LIST

Reimbursement corresponds to the percentage of the price of a service or drug paid for by the third-party payer. A 100% reimbursement means that the third-party payer covers the full price of the drug or service, with the occasional exception of certain prescription costs.

The reimbursement list lists the drugs that the third-party payer pays, in part or in full.

[See "reimbursement list" in PHIS Glossary 2009 at http:// phis.goeg.at/ index.aspx?alias=phisglossary]

NATIONAL LIST OF ESSENTIAL MEDICINES (EML)

The list of essential medicines established, adopted and published at country level. It is normally used by all healthcare facilities, including large hospitals.

To establish its list of essential pharmaceutical products, each country can adapt the WHO Model List of Essential Medicines as updated every two years by the Expert Committee on the Selection and Use of Essential Medicines.

[See WHO A model quality assurance system for procurement agencies, WHO, Geneva, 2007. Available at: http:// apps.who.int/ medicinedocs/ documents/ s14866e/ s14866e.pdf]

LAW (LEGISLATIVE PROVISION)

The laws generally define the roles, rights and obligations of all the parties concerned (see also regulations below).

[See WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at *http:// infocollections.org/ medregpack/ interface/ files/ glossary.pdf]*

MARGIN (OR DISTRIBUTION MARGIN)

The margin is the percentage added to the purchase price to obtain the sale price.

A margin is added to the total cost incurred by the producer of a product so as to generate a profit.

The wholesale margin is the gross profit of the wholesaler, expressed as a percentage added to the ex-factory price.

The pharmacy margin corresponds to the gross profit of the pharmacies, expressed as a percentage added to the wholesale price (purchase price for the pharmacy).

[See "mark-up" in PHIS Glossary 2009 , *available at http:// phis.goeg.at/ index.aspx?alias=phisglossary]*

RETAIL MARGIN

The percentage added by retailers (pharmacies) to cover their costs including profit. These costs include overhead costs incurred by the retailer such as rent, staff salaries, reconditioning as well as profit and loss. Retailer markups are not limited to the private sector: the public sector and the “other” sector can also apply markups to cover their costs.

These may vary by product; indeed, imported drugs and locally produced drugs often have different margins. Pharmacies may also charge different amounts on originator brand products and equivalent generics. In some countries, for example, the margins are higher on generic products because, even with the margin, they are considered accessible.

Maximum retailer margin Sometimes the government caps the rate or sets a maximum percentage that retailers can add. However, this maximum margin is often not respected and higher percentages are applied.

Retailer Regressive Margin In some countries, margins may vary between price categories. These margins are called "declining" because they decrease when the price of the drug increases.

In some countries where prices are not regulated or where regulations are not enforced, the retail price gap can be considerable. For drugs sold in the informal sector, it can be even higher.

[See Measuring Medicine Prices, Availability, Affordability, and Price Components (Second Edition), also available at http://www.haiweb.org/medicineprices/manual/documents.html]

WHOLESALE MARGIN

The wholesaler's margin or distribution margin is the percentage added by the wholesaler or the buying groups to cover their overheads. These costs include general expenses such as rent, security costs, electricity, staff salaries and losses. They can sometimes include the cost of transporting the drugs to the retailer. In the private sector, the mark-up also includes the profit margin; in the public and mission sectors, margin can be used to build up capital for future investment, or to cover unforeseen cost increases (for example, in the event of inflation or devaluation).

If the drugs pass through several wholesalers before reaching the patient, several distribution margins may be charged. This tends to happen when drugs move from central, urban regions to more rural areas.

Maximum wholesaler margin: In some countries, the government caps the margins or sets the maximum percentage to limit the wholesaler margin. Sometimes, however, this practice is not respected and the percentages are therefore much higher.

[See HAI-WHO, Measuring Medicine Prices, Availability, Affordability, and Price Components *(Second Edition), also available at http:// www.haiweb.org/ medicineprices/ manual/ documents .html]*

PHYSICIAN (DOCTOR OF MEDICINE)

A doctor is a person who has successfully completed university medical studies attested by an appropriate diploma and who is authorized to practice.

To be allowed to practice his profession independently, he must mostly have completed postgraduate practical training in a hospital.

The doctor can be salaried or opt for liberal status, regardless of where the services are provided.

A doctor can provide various services:

patient examination and diagnosis; prescribing medication and administering treatment for the diagnosed condition, disorder or injury; administration of medical or surgical treatment for certain types of disease, disorder or injury; advice on and application of preventive medical methods and treatments.

[Source: EUROSTAT. “Definitions and data collection specifications on health care statistics (non-expenditure data)”]

[See “physician” in PHIS Glossary 2009 *at http:// phis.goeg.at/ index.aspx?alias=phisglossary]*

The doctor (doctor of medicine) studies, diagnoses, treats and prevents ailments, diseases, traumas and other physical and mental handicaps in human beings, by applying the principles and procedures of modern medicine. To be practiced, the various professions covered by this term usually require a basic university degree in medicine, as well as postgraduate clinical training or equivalent training.

TRADITIONAL MEDICINE

Traditional medicine is the sum of knowledge, skills and practices which are based on a culture's theories, beliefs and experiences, whether or not scientifically explicable, and which are used to maintain human beings in good health as well as to prevent, diagnose, treat and cure physical illnesses and
mental.

Phytotherapy: material or preparation having therapeutic effects or other favorable effects on human health and containing processed ingredients or raw materials derived from one or more plants. In some traditions, inorganic or animal-based materials may also be present.

Complementary or alternative medicine: generally refers to a wide range of health care practices that are not part of the tradition of the country and are not integrated into the mainstream health system. We also sometimes speak of “natural”, “unconventional” and “holistic” medicine.

[See National policy on traditional medicine and regulation of herbal medicines: report of a WHO global survey *and http:// apps.who.int/ medicinedocs/ en/ d/ Js7916e/ 3.html]*

MEDIATOR

An ombudsman is a government appointee who investigates complaints made by private individuals against the government.

[See http:// wordnet.princeton.edu/]

DRUG

See *pharmaceutical product.*

RESTRICTED DRUGS

Narcotics for medical use and psychotropic substances are governed by national drug laws.

[See WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 *at http:// infocollections.org/ medregpack/ interface/ files/ glossary.pdf]*

OTC MEDICINES (NON-PRESCRIBING MEDICINES)

These are drugs that can be purchased from authorized retailers, without a prescription or supervision by a healthcare professional. They are suitable for use in self-medication for minor illnesses and symptoms.

[See WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014, *available at http:// infocollections.org/ medregpack/ interface/ files/ glossary.pdf]*

ESSENTIAL MEDICINES

The WHO definition states that “essential medicines are those which meet the priority health care needs of the population”. They are chosen on the basis of their public health utility, efficacy and safety, and comparative cost-effectiveness. Essential medicines must be available at all times within the framework of health systems, in sufficient quantities, in appropriate pharmaceutical forms, with guaranteed quality, accompanied by the necessary information and at an affordable price for the individual and the community. The concept of essential drugs is intended to be flexible and adaptable to many different situations. It is the responsibility of each country to establish its own list of medicines

essential.

[See http:// www.who.int/ topics/ essential_ medicines/ en/ index.html]

INJECTABLE MEDICINES

Sterile medicinal products for injection by bolus, by infusion or to be diluted for infusion according to one of the following modes of administration: intravenous, intramuscular, intrathecal, intra-arterial, subcutaneous, intraventricular, epidural, intravesicular, intravitreal, intrapleural and intraocular routes.

An injectable medicinal product is **ready-to-administer** when it does not need to be diluted or reconstituted and is presented in the final packaging or device, ready to be administered, or ready to be transferred into a syringe or into the administration device. For example, an infusion in a sachet without the need for an additive.

An injectable drug is ready **- to-use** when it does not need to be diluted or reconstituted before being integrated into the administration device. For example, an ampoule containing a liquid of the required concentration, which simply needs to be transferred into a syringe.

[See "Injectable medicines" in PHIS Glossary 2009 *at : http://phis.goeg.at/index.aspx?alias=phisglossary]*

PRESCRIPTION MEDICINES

Medicines that can only be dispensed from licensed pharmacies and upon presentation of a signed prescription issued by a doctor, dentist (for dental treatment only) or veterinarian (for treatment of animals only), which must be duly authorized to practice. These drugs must be dispensed by the pharmacist himself or under his supervision. Some are for restricted use (narcotics for medical use, psychotropics).

[See: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 *at http://infocollections.org/medregpack/interface/files/glossary.pdf]*

BRAND NAME (REGISTERED NAME, SPECIALTY NAME)

Name used for the marketing of any ready-to-use medicine placed on the market under a special name and packaging. A brand name can be protected *[See "brand name" in* PHIS Glossary 2009 *at: http://phis.goeg.at/index.aspx?alias=phisglossary]*

NEW CHEMICAL ENTITY (NEC)

A New Chemical Entity (NCE) is a drug product that contains no active moieties, i.e. no molecules or ions, but portions added to the molecule that convert the drug substance into an ester, salt (including a salt with a hydrogen bond or a coordination bond) or another non-covalent derivative (such as a complex, a chelate or a clathrate) of the molecule responsible for the physiological or pharmacological action of the substance. It is a chemical molecule developed by the innovative company in the early stages of scientific discovery, likely to become after clinical trials a pharmaceutical product offering an effective treatment for a given disease.

[See "new chemical entity" in PHIS Glossary 2009 at: http://phis.goeg.at/index.aspx?alias=phisglossary]

ARRANGEMENT

A prescription given, usually in written form, by a healthcare professional for a pharmacist or other therapist to dispense a drug or treatment to the patient. A prescription can consist of several items, the maximum number of which is regulated in many countries.

[See "prescription" in PHIS Glossary 2009 at: http://phis.goeg.at/index.aspx?alias=phisglossary]

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)

ISO (International Organization for Standardization) is the largest producer and publisher of International Standards. ISO is a network of national standards institutes of 159 countries, according to the principle of one member per country, of which the Central Secretariat, located in Geneva, Switzerland, ensures the overall coordination. ISO is a non-governmental organization that bridges the public and private sectors. Many of its member institutes are indeed part of the governmental structure of their country or are mandated by their government, and other member bodies are drawn exclusively from the private sector and have been established by partnerships of industry associations at the national level. . ISO thus makes it possible to establish a consensus on solutions that meet the requirements of the economic world and the more general needs of society.

Because the name "International Organization for Standardization" would have given rise to different abbreviations according to the languages ("IOS" in English and "OIN" in French), its founders opted for a short, universal name: "ISO". This name is derived from the Greek isos, meaning "equal". Whatever the country, whatever the language, the abbreviated form of the name of the organization is therefore always ISO.

[See http://www.iso.org/iso/fr/about.htm]

NON-GOVERNMENTAL ORGANIZATION (NGO, CIVIL SOCIETY ORGANIZATION)

A non-governmental organization (NGO) is a non-profit group, bringing together voluntary citizens. It is organized at the local, national or international level and aims to act for the public good. Adopting a pragmatic approach and bringing together people who share common interests, their activities can be very diverse: they provide services and fulfill humanitarian functions, relay the concerns of citizens to public authorities, monitor the implementation of policies, or further encourage the participation of civil society stakeholders in the community. Finally, they provide analysis, expertise and early warning services and contribute to monitoring and implementing international agreements. Some are specialized in specific areas such as human rights, the environment or health. Their relationship with the offices and agencies of the United Nations system varies according to their location and

their mandate.

[Free translation of the UN definition at http:// www.un.org/ dpi/ ngosection/ criteria.asp]

CIVIL SOCIETY ORGANIZATIONS

Civil *society organizations* are the many bodies through which members of society organize themselves on a voluntary basis. They represent a wide variety of interests and affinities relating to ethnic, religious and professional spheres, development or leisure. There are also organizations for the protection of

environment or human rights.

[See Governance for sustainable human development, A UNDP policy document-Glossary of key terms. *Available at* http://mirror.undp.org/magnet/policy/glossary.htm]

PAYMENT BY THE PATIENT (MODERATOR TICKET, COPY)

Contribution of the insured patient to the cost of a medical service covered by the insurer. Can be a percentage of the total cost of the service (this is called co-insurance) or an amount lump sum.

[See OECD – Medicine Prices in a Global Market, *at : http:// www.oecd.org/ document/ 36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html]*

PAYMENT

Payment made to a service provider (for example, a general practitioner or a pharmaceutical authority) for an act or service.

[See "fee for service" in the PHIS Glossary 2009 at : http:// phis.goeg.at/ index.aspx?alias=phisglossary]

PURCHASING POWER PARITIES (PPP)

Purchasing power parities (PPPs) are spatial deflators and currency conversion factors that eliminate the effects of price differences between countries, thus allowing volume comparisons of the components of Gross Domestic Product (GDP) and comparisons price levels. PPPs are calculated in three steps: first at the level of products, then groups of products or basic headings and, finally, by groups of basic headings or aggregates. Basic heading PPPs are unweighted average product PPPs. The PPPs of the aggregates are the weighted averages of the PPPs of the basic headings. The weights used are based on the expenditure associated with each basic heading. At each stage, the PPPs correspond to price ratios. They illustrate how many units of currency A must be spent in country A to obtain the same volume of a product, basic heading or aggregate that X units of currency B can buy in country A. country B. In the case of a product, "same volume" must be understood as "identical volume". However, when dealing with a complex assortment of goods and services making up an aggregate such as GDP, "same volume" does not mean "an identical basket of goods and services". The composition of the basket may vary between countries according to economic, social and cultural differences; each basket must nevertheless provide satisfaction, or have an equivalent utility. PPPs are also referred to as "parities".

[See "purchasing power parity" in PHIS Glossary 2009 at http:// phis.goeg.at/ index.aspx?alias=phisglossary]

NURSES AND MIDWIVES

The category "nursing and midwifery personnel" covers health professionals who plan, provide, and evaluate treatment, support and care services for people experiencing the effects of aging or suffering from injury, illness or other physical or mental disability, or subject to the health risks induced by pregnancy, childbirth and the postnatal period. The professions concerned most often require knowledge and skills acquired in a higher education establishment. They include, for example, those of nurse practitioner, clinical nurse, public health nurse, nurse anesthetist, private nurse and private midwife.

PHARMACY

A place that, in accordance with local legal provisions and definitions, may be used for the provision of pharmacy services within the community or health facility.

[Definition of "pharmacy" in Operational package for assessing, monitoring and evaluating country pharmaceutical situations *(WHO), available at : http:// www.who.int/ medicines/ publications/ WHO_TCM_2007.2/ en/]*

PHARMACIST

A pharmacist is a person who has successfully completed university studies in pharmacy attested by an appropriate diploma and who is, as such, authorized to practice. He can be an employee or opt for liberal status, regardless of where the services are provided.

A pharmacist can provide various services: preparation of drugs, or supervision of the preparation, based on the prescription of a doctor or a dentist; formulation; monitoring prescriptions to ensure that recommended doses are not exceeded and that instructions are understood by patients; administration of medications and advice on possible incompatibilities; dispensing of drugs in hospitals or sale in pharmacies.

[Source: according to EUROSTAT, "Definitions and data collection specifications on health care statistics (non-expenditure data)"]

[See "pharmacist" in PHIS Glossary 2009 *at http:// phis.goeg.at/ index.aspx?alias=phisglossary]*

Pharmacists store, preserve, compound, test, dispense and control medical products and therapies to optimize human health. The various professions covered by this term usually require practical and theoretical university training in pharmacy, pharmaceutical chemistry or a related field. There are, depending on the country, hospital, industrial, dispensing pharmacists.

PHARMACIST

Health professional trained and authorized to dispense drugs.

PHARMACOVIGILANCE

Science and activities relating to the detection, assessment, understanding and prevention of adverse effects or other drug-related problems.

[See WHO The importance of pharmacovigilance, available at: http://apps.who.int/medicinedocs/en/d/Js4893e/#Js4893e]

The science and procedures involved in monitoring the safety of drugs, reducing the risks associated with them and increasing the benefits derived from their use. This is an essential function of public health.

Pharmacovigilance encompasses the following activities:

- Collection and administration of drug safety data.

- Examination of the data in order to detect any new problem or any evolution in matter of safety.

- Data evaluation and decision making in case of safety issue.

- Implementation of measures (particularly of a regulatory nature) to protect public health.

- Relations with stakeholders

- Examination of the results of the measures taken and the main procedures.

Are directly concerned by pharmacovigilance:

- Patients, as drug users.

- Doctors, pharmacists, nurses and all other health professionals working with drugs.

- Regulatory authorities, in particular the European Medicines Agency and bodies responsible in Member States for monitoring the safety of medicinal products

- Pharmaceutical companies, and companies importing or distributing drugs.

[Source: European Commission (section on pharmaceuticals and pharmacovigilance), http://ec.europa.eu/enterprise/pharmaceuticals/pharmacovigilance/pharmacovigilance_en.htm]

[See "Pharmacovigilance" in PHIS Glossary 2009 at http://phis.goeg.at/index.aspx?alias=phisglossary]

RISK MANAGEMENT PLAN

A risk management plan serves to describe not only what is known about the safety of a medicine at any given time, but also the potential risks that still need to be clarified and how the initiating pharmaceutical company intends to investigate them. .
The initiator *(sponsor)* must develop a so-called "pharmacovigilance" plan to monitor the new drug once it is approved and to assess the need to undertake new risk reduction activities (additional training material, in particular for the prescription, restrictions on the promotion and use of the drug), which should, if necessary, be detailed in a risk reduction plan.

[Adapted from The Australian Prescriber, *Australian Government, http:// www.australianprescriber.com/ magazine/ 33/1/10/11/]*

NATIONAL PHARMACEUTICAL POLICY IMPLEMENTATION PLAN

This document expresses in writing the plans of the government to implement the national drug policy. It defines the activities and responsibilities and sets the budget and schedule.

[Definition of "national medicines policy implementation plan" in Operational package for assessing, monitoring and evaluating country pharmaceutical situations *(WHO), available at: http:// www.who.int/ medicines/ publications/ WHO_TCM_2007.2/ in/]*

AUTHORIZED ENTRY POINT

Point of entry where medicines can enter or leave a country under the control of the authorities, i.e. point where customs formalities take place.

[Adapted from Managing Drug Supply, Second Edition, Management Sciences for Health. *Available at http:// erc.msh.org/ newpages/ english/ drugs/ intro_pg.pdf]*

NATIONAL HEALTH POLICY

A national health policy is a written document setting out the government's medium and long-term objectives and priorities in the health sector as well as the related strategies.

[See definition of "national health policy" in Operational package for assessing, monitoring and evaluating country pharmaceutical situations *(WHO), available at : http:// www.who.int/ medicines/ publications/ WHO_TCM_2007.2/ in/]*

NATIONAL PHARMACEUTICAL POLICY (NPP)

A pharmaceutical policy is both a commitment to achieve a goal and a guide to action. It presents and prioritizes the government's medium and long-term objectives in the pharmaceutical sector, and specifies the main strategies for achieving them. It also provides a framework for coordinating the activities of the pharmaceutical sector. The PPN covers the public and private sectors and concerns all the main players in the field. It is important that it takes the form of an official printed document, and thus testifies in good and due form to the aspirations, objectives, decisions and commitments. In the absence of such a guidance document, there would be no overall vision of the action required and certain public authorities' measures might not be well aligned, the objectives and responsibilities being neither clearly defined nor well understood.

This document should be developed through systematic consultation with all interested parties. This process should be an opportunity to define objectives, priorities and strategies and to encourage involvement.

[See How to develop and implement a national drug policy and http://apps.who.int/medicinedocs/fr/d/Js5409f/]

TOTAL POPULATION

Total population refers to *de facto population,* which includes all residents regardless of legal status or citizenship, with the exception of refugees who are not permanently settled in their adopted country, generally included in the population of their country of origin.

[Source: World Bank, data and statistics]

PRIMARY HEALTH CARE POSTS

Positions in which primary health care is provided.

Primary health care is essential or general health care provided where the patient normally goes first. They are considered complete when the provider assumes the overall coordination of the care provided in response to the patient's health problems, whether these are biological, behavioral or social.

They are generally provided by doctors – general practitioners, interns, obstetricians and pediatricians – but more and more often by other professionals such as nurse practitioners or medical assistants.

[See "primary health care unit" in PHIS Glossary 2009 at http://phis.goeg.at/index.aspx?alias=phisglossary]

PRESCRIBER

The healthcare professional legally authorized to issue a prescription.

PRESELECTION

Activities undertaken to define the need for a product or service, to solicit expressions of interest from companies wishing to supply them, and to review them against technical specifications and the establishment where they are prepared, by reference to current Good Manufacturing Practice (GMP) standards. Trained and qualified inspectors examine them and the manufacturing establishment against current standards.

Once the product or service is approved and the establishment has the authorization to deliver it, the other central purchasing bodies are informed of this decision. Prequalification is required for all medicines, regardless of their composition and their production/registration centre, but the amount and type of information that the supplier must give to the central purchasing body for evaluation purposes may differ.

[See: Model quality assurance system within purchasing centres, *WHO, Geneva 2007, available at: http:// apps.who.int/ medicinedocs/ documents/ s14866e/ s14866e.pdf]*

ACTIVE INGREDIENT

The chemical substance present in a pharmaceutical product and responsible for its therapeutic effect. Some pharmaceutical products (so-called combinations) contain two or more active ingredients.

[See OECD – Medicine Prices in a Global Market, *at : http:// www.oecd.org/ document/ 36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html]*

GUIDING PRINCIPLES APPLICABLE TO MEDICINE DONATIONS

In 1999, WHO published guidelines for drug donations based on four main principles. The first essential principle is the following: a drug donation must be as useful as possible to the beneficiary. This includes all donations being based on expressed need and discouraging unsolicited drug donations. The second principle is that a donation must be made with full respect for the wishes and authority of the recipient, and must comply with the health policies and administrative procedures in force in the country. The third is that there should not be double standards when it comes to quality. If the product does not meet quality standards in the donor country, it cannot be donated. The fourth principle is that there must be communication

effective between donor and recipient. Donations should be based on need expressed and not to be sent without having been requested.

WHO recommends that each recipient country formulate its own guidelines for drug donations based on those formulated at the international level.
These national guiding principles must then be formally presented and clarified to the donor community. They can only be applied once presented and officially published.

[See "guidelines for medicines donations" in WHO Drug donations guidelines pdf *at: http:// apps.who.int/ medicinedocs/ pdf/ whozip52e/ whozip52e.pdf]*

INTERNATIONAL REFERENCE AWARD

In the survey conducted by WHO and HAI to measure medicine prices, availability, affordability and price components, medicine prices are expressed as ratios against a set of standard reference prices for facilitate national and international comparisons. The median prices contained in MSH's International Drug Price Indicator Guide have been selected as the most useful standard as they are frequently updated, always available and relatively stable. These prices are recent supply prices granted by for-profit and non-profit suppliers to developing countries, for products from multiple sources.

The reference prices are more or less representative depending on the number of suppliers who communicated their prices for each product. For example, if a medicine has a single, high supplier price, you will get a low median price ratio (MPPR), which can be misinterpreted as low national prices.

[Adapted from WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situations: Guide for coordinators and data collectors, *WHO, Geneva, 2007.*
Available at: http:// apps.who.int/medicinedocs/documents/s14877e/s14877e.pdf]

MANUFACTURER'S SELLING PRICE (EX-FACTORY PRICE)

Price at which the manufacturer sells the medicine.

[See HAI/WHO, Measuring Medicine Prices, Availability, Affordability and Price Components *(Second Edition) and : http://www.haiweb.org/medicineprices/manual/documents.html]*

The ex-factory price is the price displayed by the manufacturer. In some countries, we also speak of “list price”. Discounts and other advantages offered by the manufacturers result in a lower price than the ex-factory price.

[See OECD – Medicine Prices in a Global Market, *at : http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html]*

FINAL PRODUCT

This is a product that has gone through all the stages of production, including packaging in its final packaging and labeling.

[See WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 *at http://infocollections.org/medregpack/interface/files/glossary.pdf]*

GROSS DOMESTIC PRODUCT (GDP)

GDP is the value of all goods and services provided in a country by residents or non-residents, whether charged against domestic or foreign claims.

[See http://www.who.int/whosis/indicators/WHS09_IndicatorCompendium_20090701.pdf]

Gross domestic product is an aggregate measure of production: it is equal to the sum of the gross values added of all resident producing units, plus any taxes, less any subsidies, on products not included in the value of production. To calculate it, one can either calculate the sum of final uses of goods and services (i.e. all uses less intermediate consumption), measured at the purchase price and reduced by the value of imports of goods and services, i.e. the sum of the primary incomes distributed by the resident producer units.

[See definition of “gross domestic product” at http://unstats.un.org/unsd/snaama/glossresults.asp?gID=5]

COUNTERFEIT MEDICAL PRODUCT

Refers to a product giving false indications of its identity and/or origin. This information may be present on the product, its container, packaging or labeling. Counterfeiting concerns both branded and generic drugs.

Among the counterfeit products, there are some that contain the right ingredients or the wrong ingredients, or even no active ingredient, and there are others where the active ingredient is in insufficient quantity or whose packaging has been falsified. Patent violations or disputes should not be confused with the counterfeiting of medical products.

A medical product (branded or generic) prohibited for sale in one country but authorized in another is not considered counterfeit.

Batches of poor quality or that do not meet standards or that do not respect good manufacturing practices (GMP) or distribution (GDP) but which are legally manufactured medical products should not be confused with counterfeits.

[See "counterfeit medical product" in PHIS Glossary 2009 *at : http://phis.goeg.at/index.aspx?alias=phisglossary]*

PHARMACEUTICAL PRODUCT (DRUG)

Any substance or pharmaceutical product for human or veterinary use designed to modify or explore physiological systems or disease states, for the benefit of the person to whom it is administered. The terms "drug" and "pharmaceutical product" are used interchangeably in this document.

[See WHO A model quality assurance system for procurement agencies, *WHO, Geneva, 2007. Available at: http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf]*

In a more restrictive sense, the term "pharmaceutical product" refers to a single product defined by the nature and potency of its active principle, its pharmaceutical form and its route of administration.

[See: ICH Consensus Guideline Released for Consultation on 10 May 2005 at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073307.pdf]*

ORIGINAL PHARMACEUTICAL/ORIGINAL BRAND

In general, the product that was first authorized on the market (normally as a patented product) on the basis of documentation relating to its efficacy, safety and quality, according to the requirements in force at the time of permission. The original product always has a brand name (eg Valium). However, the latter may vary from country to country.
to the other.

Some substances, such as prednisolone and isoniazid, are so old that no original product can be identified and the patent has never been filed.

[See the definition of "originator pharmaceutical product" in HAI-WHO, Measuring Medicine Prices, Availability, Affordability and Price Components *(Second Edition) at http:// www.haiweb.org / medicineprices/ manual/ documents.html]*

WHO PRE-SELECTION PROGRAM

Launched in 2001 in partnership with UNAIDS, UNICEF and the United Nations Population Fund and with support from the World Bank, the WHO prequalification program addresses quality issues commonly associated with medicines in the field of HIV/AIDS, tuberculosis, malaria and reproductive health research. It provides for rigorous evaluation of pharmaceutical product dossiers, inspection of production sites and contract research organizations, prequalification of pharmaceutical quality control laboratories, and promotes quality-assured medicines.

[See Prequalification of Medicines Program - Update for 2006 *(WHO), available at http:// apps.who.int/ medicinedocs/ documents/ s14150e/ s14150e.pdf]*

PROMOTION

Means any information and incentive activity carried out by manufacturers and distributors to prescribe, buy and/or use medicines.

[See C:\Documents and Settings\CVialle\Desktop\Country profile - Instructions and glossary 14 Sept 2010\WHO. A model quality assurance system for procurement agencies.pdf. The Criteria for Medicinal Drug Promotion document *is available at: http:// apps.who.int/ medicinedocs/ documents/ whozip08e/ whozip08e.pdf]*

DIRECT TO CONSUMER MEDICINE ADVERTISING (PDC)

This concerns advertising concerning medicinal products and aimed directly at the general public, in particular in the press, on television and on the radio.

[See OECD – Medicine Prices in a Global Market, *at : http:// www.oecd.org/ document/ 36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html]*

MEDIAN PRICE RATIO (MPR)

In the WHO and HAI survey “Measuring Medicine Prices, Availability, Affordability and Price Components”, medicine prices are not expressed in monetary units, but as ratios compared to international prices of

reference :

$$\text{Median price ratio (MPR)} = \frac{\text{Local median unit price}}{\text{Reference international unit price}}$$

The ratio therefore indicates the size of the difference, more or less, between the local price of the drug and the international reference price. For example, a median price ratio of 2 would mean that the former is twice the latter.

This instrument facilitates international comparisons of drug prices.

Contrary to the arithmetic mean, the median value makes it possible to attenuate the disturbing influence of extreme values; it is therefore more representative. The magnitude of price changes is represented by the interquartile range. A quartile is each of three values that divide the sorted data into four equal parts. The interquartile range corresponds to the central half of the observed values, ie the interval between the 25th and 75th percentiles.

[See HAI/ WHO, Measuring Medicine Prices, Availability, Affordability and Price Components *(Second Edition) at : http:// www.haiweb.org/ medicineprices/ manual/ documents.html]*

REGULATIONS

The second stage of the legislative process (the first being legislation, see above). The regulations specifically aim to provide the legal framework to achieve the administrative and technical objectives of the legislation.

[See Model quality assurance system within purchasing centres, *WHO, Geneva, 2007. Available at: http:// apps.who.int/ medicinedocs/ documents/ s17075f/ s17075f.pdf]*

ANTIMICROBIAL RESISTANCE

Antimicrobial resistance is the appearance and spread of germs resistant to cheap and effective "first-line" drugs. The emergence of resistance to antimicrobials is most evident for the bacterial infections which contribute the most to morbidity in humans: diarrheal diseases, respiratory infections, meningitis, sexually transmitted infections, nosocomial infections.

Prominent examples include penicillin-resistant *Streptococcus pneumoniae ,* vancomycin-resistant enterococci, methicillin-resistant Staphylococcus aureus, polydrug-resistant Salmonella and multidrug-resistant tuberculosis.
Of particular concern is the development of resistance to drugs commonly used to treat malaria, and the same is true for HIV. *[See : http:// www.who.int/ mediacentre/ factsheets/ fs194/ fr/ index.html]*

SUMMARY OF PRODUCT CHARACTERISTICS

Product information as approved by the regulatory authority. The summary is the basis of the documentation provided to health personnel. It is also used to inform the consumer, through labels and leaflets, and to control drug advertising.

[See WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014, *available at http:// infocollections.org/ medregpack/ interface/ files/ glossary.pdf]*

GROSS NATIONAL INCOME (GNI)

Gross National Income (GNI) is the sum of value added by all resident producers, plus taxes (minus subsidies) not included in the valuation of products plus net primary income receipts from the rest of the world (compensation of employees and income from property).

[See "gross national income" : http://www.who.int/whosis/indicators/WHS09_IndicatorCompendium_20090701.pdf]

Gross National Income (GNI) equals GDP minus net taxes on production and imports, compensation of employees and property income payable to the rest of the world, plus the corresponding items receivable from the rest of the world (in other words, GDP less primary income payable to non-resident units plus primary income receivable from non-resident units); GNI at market price is also the aggregate value of the gross balances of primary income of all sectors (GNI is identical to gross national product (GNP) as it is traditionally understood in national accounts).

[See "gross national income" at http://unstats.un.org/unsd/snaama/glossresults.asp?gID=8]

PRIVATE SECTOR

In a mixed economy, the private sector corresponds to the part of the economy not controlled by the State and whose functioning is part of a market; private enterprise.

[See "private sector" Governance for sustainable human development, A UNDP policy document-Glossary of key terms, *available at:* http://mirror.undp.org/magnet/policy/glossary.htm]

PUBLIC SECTOR (CIVIL SERVICE)

The public sector refers to the part of the economy that is not owned by the private sector (state ownership or common ownership). The term encompasses the State, local communities, national industries and public enterprises.

[See Governance for sustainable human development, A UNDP policy document-Glossary of key terms, *available at:* http://mirror.undp.org/magnet/policy/glossary.htm]

SOCIAL SECURITY

Social security funds, as defined in national health accounts, represent special types of institutional units that can be found at any level of government: central, regional or local. Social security systems are social insurance systems that cover the whole community or large subsets of the community. They are imposed and controlled by governments and generally involve the payment of compulsory contributions by employees or employers, or by both. The conditions under which benefits are paid to beneficiaries are determined by the general government. These systems cover a wide variety of programs which consist of providing benefits, in cash or in kind, depending on the various circumstances; old age, invalidity or death, survivorship, sickness and maternity, accidents at work, unemployment, family allowances, medical care, etc.

There is generally no direct link between the amount of the contribution paid by an individual and the risk to which the latter is exposed. Social security systems must be distinguished from retirement pension systems and other social insurance systems, which are determined by mutual agreement between certain employers and their employees, systems in which benefits are based on contributions.

[See "social security" in Guide to Producing National Health Accounts, *available at: http://www.who.int/nha/docs/English_PG.pdf]*

CIVIL SOCIETY

Civil *society* is made up of individuals and groups, organized or not, who interact in the social, political and economic domains and who are subject to formal and informal laws and rules. Civil society offers a wide range of perspectives and values that seek expression in the public sphere.

[See "civil society" in Governance for sustainable human development, A UNDP policy document-Glossary of key terms. *Available at* http://mirror.undp.org/magnet/policy/glossary.htm]

AMBULATORY CARE

Ambulatory care includes medical and paramedical services provided to outpatients. An outpatient is defined as a person who is not formally admitted to a facility (for example, a physician's private practice) and is not staying there overnight. It is therefore a person who presents to a health care service for a consultation or treatment and leaves this service a few hours after the start of the consultation without a formal admission procedure having been carried out.

It should be noted that the term "ambulatory care" within the meaning of the OECD System of Health Accounts (SHA) has a broader meaning than that used in some national accounting systems, where it refers only to care provided in hospital outpatient departments. In the SCS, anyone who uses outpatient facilities without being hospitalized day or night is considered an outpatient [Source: OECD, System of Health Accounts]

[See "out-patient care" in PHIS Glossary 2009 *http://* , *at the address phis.goeg.at/ index.aspx?alias=phisglossary]*

HOSPITAL CARE

An "inpatient" is a patient officially admitted for treatment and/or care, for a stay of at least one night, in a hospital or other establishment providing care with accommodation.

Hospital care is provided mainly in hospitals, but also in nursing homes and other care structures with accommodation, as well as in establishments classified in the ambulatory sector because of the nature of the care they provide, but which have a secondary activity of hospital care.

The term "hospital care" used in the OECD report entitled "System of Health Accounts (SHA) has a broader meaning than that used in some national accounting systems, where it refers exclusively to care provided in hospitals . In the SCS, hospital care includes care provided in prison or military hospitals, tuberculosis hospitals and sanatoriums.

They cover accommodation associated with medical treatment when the latter constitutes the main reason for the patient's stay.
On the other hand, accommodation offered by medico-social establishments whose medical activity is significant but not preponderant should not be counted in health care. This category includes, for example, homes for the handicapped, nursing homes and establishments for drug addicts.

[Source: OECD, System of Health Accounts]

[See "In-patient care" in PHIS Glossary 2009 *at : http:// phis.goeg.at/ index.aspx?alias=phisglossary]*

AMAZING

This legal term encompasses all the substances covered by the Single Convention on Narcotic Drugs of 1961 and by the Protocol of 1972 amending the said Convention (in particular, opiates, opioids, cocaine and cannabis).

[See: http://www.incb.org/pdf/f/conv/convention_1961_fr.pdf]

SUBSTITUTION BY A GENERIC PRODUCT

Practice which consists in substituting a product, sold under a brand name or a generic name (generic with or without brand) by an equivalent pharmaceutical product, generally less expensive but which contains the same principle(s) assets).

[See Model Quality Assurance System Within Central Procurement *Organizations, WHO, Geneva, 2007, at: http://apps.who.int/medicinedocs/documents/s17075e/s17075e.pdf]*

POST-MARKETING SURVEILLANCE

Post-marketing surveillance involves testing drug samples to assess the quality of drugs that have already been approved.

[Definition of "post-marketing surveillance" in Operational package for assessing, monitoring and evaluating country pharmaceutical situations *(WHO), available at : http://www.who.int/medicines/publications/WHO_TCM_2007.2/en/]*

LICENSING SYSTEM

National legislative provisions which stipulate which entities will be responsible for producing, importing or supplying pharmaceutical products, which qualifications the persons working in the distribution agency will have to possess and who will be responsible for dispensing and selling the products.

[See WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 *at http://infocollections.org/medregpack/interface/files/glossary.pdf]*

WHO CERTIFICATION SYSTEM

The WHO certification system provides importing countries with information on:

(a) the status of the pharmaceutical product;
(b) the status of the manufacturer of the pharmaceutical
product; (c) the quality of the batches of the exported
pharmaceutical product; d) the product itself (information approved in the exporting country).

By December 1994, the WHO certification system had been accepted by the health authorities of 138 countries exporting and importing pharmaceutical products, which testifies to their desire to share responsibility for the quality of the drugs subject to 'international exchanges.

[See: Use of the WHO certification scheme on the quality of pharmaceutical products moving in international commerce, *available at: http://apps.who.int/medicinedocs/en/d/Jwhozip43e/4.2.html]*

NATIONAL HEALTH SERVICE SYSTEMS (NATIONAL HEALTH INSURANCE)

National health service systems have three main characteristics: they are mainly financed by state revenues, they provide medical coverage to the entire population, and their services are delivered through a network of providers. public.

[See definition of "National health services systems" in A practitioner's guide: Health Financing Revisited *(World Bank, 2006) and at http://siteresources.worldbank.org/INTHSD/Resources/topics/Health-Financing/HFRFull.pdf]*

CHANGE RATE

Several websites provide exchange rates and tools for obtaining values in US$. For example, the site http://www.oanda.com/currency/historical-rates automatically calculates the average of the exchange rates for a given period (under "currency tools").

MORTALITY RATE

The mortality rate is an estimate of the proportion of a population that dies during a given period. The numerator is the number of people who die during the period, the denominator the number of people exposed to the risk of death (usually the average population).

[See "mortality rate" in PHIS Glossary 2009 *at http://phis.goeg.at/index.aspx?alias=phisglossary]*

UNDER-5 MORTALITY RATE

The under-5 mortality rate is the probability of dying before the age of 5. It is expressed as the number of deaths among children in this category, for
1,000 live births.

[See: http://unstats.un.org/unsd/demographic/products/socind/health.htm#tech]

CHILD MORTALITY RATE

The infant mortality rate is the total number of infants who die before the age of one year per 1,000 live births in one year. This is an approximation of the number of deaths per 1,000 children who are born alive and then die in the following year.

[See "infant mortality rate" at http://unstats.un.org/unsd/demographic/products/socind/health.htm#tech]

MATERNAL MORTALITY RATE

The maternal mortality ratio is the number of maternal deaths per 100,000 live births recorded during a specified period (usually one year).

A maternal death means the death of a woman during pregnancy or during the 42 days following childbirth, regardless of the duration and location of the pregnancy, for any cause determined or aggravated by the pregnancy or its management, but neither accidental nor fortuitous.

Complications during pregnancy and childbirth are a major cause of death and disability among women of reproductive age in developing countries. The maternal mortality rate represents the risk associated with each pregnancy, ie the obstetrical risk. It is also an indicator of Millennium Development Goal 5 (improve maternal health).

[Based on the definition of "maternal mortality ratio" at : http:// www.who.int/ whosis/ indicators/ compendium/ 2008/3mrf/ en/]

VALUE ADDED TAX (VAT)

VAT and GST may be levied on sales. These taxes vary from country to country and sometimes even from state to state within the same country. In many countries, medicines are exempt from VAT or GST, while others levy it at each stage of the distribution chain. Each player in the distribution chain pays the costs with VAT and then adds the VAT to its selling price. The VAT is therefore reimbursed to the actors so that only the final buyer pays it.

Some countries subject medicines to a Goods and Services Tax (GST) and/or other national or regional taxes.

[Adapted from HAI-WHO, Measuring Medicine Prices, Availability, Affordability and Price Components *(Second Edition), available at http:// www.haiweb.org/ medicineprices/ manual/ documents.html]*

PHARMACY TECHNICIANS AND ASSISTANTS

Pharmacy technicians and assistants perform a variety of tasks associated with dispensing medical products, under the supervision of a pharmacist or other healthcare professional. The professions covered by this expression usually require knowledge and skills acquired during pharmacy studies in a higher education institution. Depending on the country, there are technicians, assistants or pharmacy assistants, among others.

THIRD-PARTY PAYMENT

Any entity, public or private, that pays or insures health or medical costs on behalf of beneficiaries or recipients.

[See OECD – Medicine Prices in a Global Market, *at : http:// www.oecd.org/ document/ 36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html]*

AUTHORIZATION HOLDER

A natural or legal person who has a marketing authorization (sometimes called a “licence”) for a pharmaceutical product.

[See WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at *http:// infocollections.org/ medregpack/ interface/ files/ glossary.pdf]*

URLs

The acronym corresponding to Universal Resource Locator and designating the address of a Web page on the global web.

RATIONAL USE OF MEDICINES

Rational use of medicines means that patients receive medicines appropriate to their clinical needs, in doses suited to their individual requirements, for an adequate period, and at the lowest cost to themselves and to their community.

[See Promoting the rational use of medicines: key elements, *WHO, Geneva, 2002. Available at: http://whqlibdoc.who.int/hq/2002/WHO_EDM_2002.3_eng.pdf]*

DIRECT PAYMENTS

Payments made by a health care consumer that are not reimbursed by a third-party payer.

Includes cost sharing and informal payments to health care providers.

Co-payment: provision of a health insurance scheme or third-party payment system under which the covered individual must bear part of the cost of the medical care he receives. It is to be distinguished from a health insurance premium, a contribution or a tax which are paid whether there is medical consumption or not.

It can take the form of a deductible, coinsurance or co-payment.

Deductible: amount that the insured person must pay under a health insurance contract before any benefit can be paid. Deductibles are usually expressed as
of an annual amount.

Once this amount is reached, the insurer pays up to 100% of the approved amounts for
covered services provided during the rest of the year.

Co-payment: A form of co-payment in which a fixed sum is paid for a service.

Co-insurance: contribution to expenses in the form of a defined share of the cost of the service.

[Adapted from OECD, System of Health Accounts,
http://www.oecd.org/document/8/0,3343,en_2649_34631_2742536_1_1_1_1,00.html]