Argentina

PHARMACEUTICAL COUNTRY PROFILE

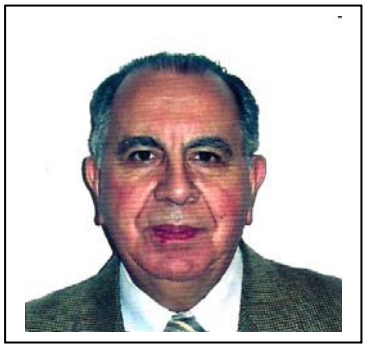
Foreword

This 2010 Pharmaceutical Country Profile for Argentina has been produced by the Ministry of Health with support of the World Health Organization.

This document contains information on structures, process and outcomes of the pharmaceutical sector in Argentina. Some of the data comes from global sources (e.g. the World Health Statistics) or from surveys conducted in the previous years, while other pieces of information have been collected at country level in 2010. The sources of data for each piece of information are presented in the tables that can be found at the end of this document.

On the behalf of the Ministry of Argentina, I wish to express my appreciation towards Catalina de la Puente from Isalud University for her contribution to the data collection and to the development of this profile.

It is my hope that partners, researchers and all those that are interested in the pharmaceutical sector of Argentina will find this profile a useful tool in their activities.



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Introduction

This Pharmaceutical Country Profile provides data on structures, processes and outcomes of the pharmaceutical sector of Argentina. The aim is to put together existing information and to make all relevant information on the pharmaceuticals sector available to the public in a user-friendly format. In 2010, country profiles similar to this one have been developed for 13 pilot countries. During 2011, the World Health Organization plans to support all WHO Member States to develop similar country profiles.

The information is categorized in 8 sections, namely: (1) Health and Demographic data, (2) Health Services, (3) Policy Issues, (4) Regulation, (5) Medicines Financing, (6) Supply of Pharmaceuticals, (7) Rational Use of Medicines, and (8) Household Surveys. The indicators have been divided into two categories, namely "core" (most important) and "supplementary" (useful if available). The narrative profile is based only on the core indicators; while the tables in the annexes present all indicators. For each piece of information, we have tried to indicate the year and source of the data; these are used to build the references in the profile and are also indicated in the tables. If key national documents are available on-line, links are provided to the source documents so that the user can easily access these documents

The selection of indicators for the profiles has involved all technical units working in the Essential Medicines Department of the World Health Organization as well as experts from WHO Regional and Country Offices, Harvard Medical School, Oswaldo Cruz Foundation (known as Fiocruz), University of Utrecht, the Austrian Federal Institute for Health Care and representatives from 13 pilot countries. Data collection in the pilot countries was conducted using a user-friendly electronic questionnaire that included a comprehensive glossary. Countries were requested not to conduct any

additional surveys, but only to enter the results from previous surveys and to provide information available at the central level. To facilitate the work of national counterparts, the questionnaires were pre-filled using all data available at WHO HQ before being sent out to countries. A coordinator was nominated for each of the 13 pilot countries. The coordinator for Argentina was Catalina de la Puente.

The completed questionnaires were then used to produce the country profiles. In order to do this in a structured and efficient manner, a text template was developed. Member states took part in the development of the profile and, once the final product was ready, an officer from the Ministry of Health certified the quality of the information and gave formal permission to publish the profile on the web site of WHO.

This profile will be regularly updated by country teams. If you have any suggestions on corrections to make please send them to C. de la Puente, catadelapuente@gmail.com.ar, 413 No 1940 entre 139 y 141. Villa Elisa. La Plata. Buenos Aires, Argentina (1894).

Section 1 - Health and Demographic Data

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

1.1 Demographics and Socioeconomic Indicators

The total population of Argentina in 2010 was 40,518,000 with an annual population growth rate of 0.91%. The annual GDP growth rate is 0.9% [1]. The GNI per capita is US$ 7,200 [2]. After the 2001-2002 crises, Argentina's average annual GDP growth was approximately 8.5 %. In 2008 it dropped to 6.8% and in 2009 to 0.9% [1].

1.2 Mortality and Causes of Death

The life expectancy at birth for men is 71.6 years and for women is 79.1 years [1]. The infant mortality rate is 12.5/1,000 live births. For children under the age of 5, the mortality rate is 14.5/1,000 live births. The maternal mortality rate is 40/100,000 live births.

The top 10 diseases causing mortality in Argentina are:

1. Heart diseases
2. Malignant tumors
3. Cerebrovascular diseases
4. Acute respiratory infections
5. Accidents
6. Respiratory failure
7. Septicemia
8. Urinary system diseases
9. Diabetes mellitus
10. Chronic lower respiratory diseases [3].

Section 2 - Health Services

This section provides information regarding health expenditures and human resources in Argentina. The contribution of the public and private sector to overall health expenditure is shown and the specific information on pharmaceutical expenditure is also presented. Data on human resources for health and for the pharmaceutical sector is provided as well.

2.1 Health Expenditure

In Argentina, the government[1] annual expenditure on health is ARS 41,104 million (US$ 13,217 million), with a total per capita public expenditure on health of ARS 1044.41 (US$ 336). The government annual expenditure on health represents 13.9% of the total government budget [4].

In Argentina, the public health care provides coverage to the total population. This is composed of primary health care units (first level) and hospitals (second and third level). Therefore, 100% of the population is covered under this service. Both levels provide medicines free of charge. Outpatient medication drug coverage represents 80% of consultations in primary care centers [5].

The annual growth rate of the total pharmaceuticals market value is 25 % [1].

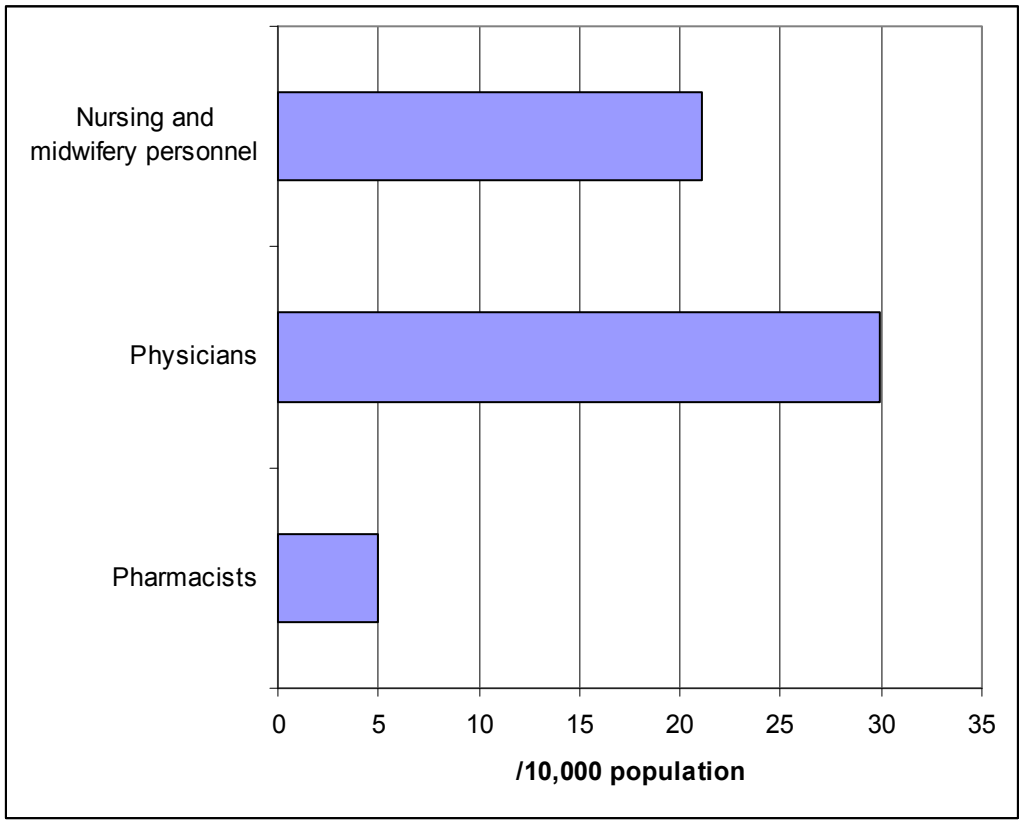
2.2 Health Personnel

The health workforce is described in the table below and in figure 1.

Licensed pharmacists (all sectors)	4.95/10,000
Physicians (all sectors)	29.9/10,000
Nursing and midwifery personnel (all sectors)	21.1/10,000

[1] According to the NHA definition, by "government expenditure" it is meant all expenditure from public sources, like central government, local government, insurance funds and parastatal companies.

Figure 1: The density of the Health Workforce 2010 in Argentina (all sectors)



In Argentina, there is not a strategic plan for pharmaceutical human resource development in place [6].

2.3 Health Infrastructure

The health centre and hospital statistics are described in the table below.

Hospitals (1,271 public hospitals)	0.82/10,000
Hospital beds	38/10,000
Primary public health care units and centres	1.6/10,000 (if all health facilities without in-patient services are included: 3.6) [3]

Section 3 - Policy Issues

This section addresses the main structure of the pharmaceutical policy in Argentina. Information about the capacity for manufacturing medicines and regulations regarding patents is also provided.

3.1 Policy Framework

In Argentina, a National Health Policy (NHP) exists. It was updated in 2004. The New Federal Plan is currently being prepared and updated and will be published in July 2010 [7]. An official National Medicines Policy document does not exist in Argentina. A group of policies addressing pharmaceuticals exists. The Federal Health Plan contains some drug guidelines. There are also standards and laws linked to pharmaceutical policy and drug provision programs to improve access. The Ministry of Health has a Drugs Committee that develops and discusses policies that will be implemented.

The group of policies cover:

Selection of essential medicines	Yes
Medicines financing	Yes
Medicines pricing	No
Procurement	Yes
Distribution	Yes
Regulation	Yes
Pharmacovigilance,	Yes
Rational use of medicines	Yes
Human resource development	Yes
Research	Yes
Monitoring and evaluation	Yes
Traditional Medicine	No

An NMP implementation plan does not exist [5]. Access to essential medicines/technologies as part of the fulfillment of the right to health, is not recognized in the constitution or national legislation [8]. There are official written guidelines on medicines donations [9]. The pharmaceutical policy implementation is being regularly monitored. The Medicines Commission of the Ministry of Health is responsible for the monitoring of the pharmaceutical policy.

There is a national good governance policy for the pharmaceutical sector in Argentina. The national and provincial Ministries are jointly responsible for this policy through the Federal Health Council (COFESA). There are two general laws for managing conflicts of interest and sanctions (not limited to pharmaceutical matters only). The Public Ethics Law covers the public area and the Professional Practice Law covers the private area.

There is a formal code of conduct for public officials (Public Ethics Law). There is no whistle-blowing mechanism allowing individuals to raise a concern about wrongdoing occurring in the pharmaceutical sector of Argentina [5] [8] [10].

3.2 Intellectual Property Laws and Medicines

Argentina is a member of the World Trade Organization. The country has patent law. National Legislation has been modified to implement the TRIPS Agreement. Argentina is not eligible for the transitional period to 2016.

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

Compulsory licensing provisions that can be applied for reasons of public health	Yes
Bolar exceptions	Yes
Parallel importing provisions	Yes

The country is engaged in initiatives to strengthen capacity to manage and apply intellectual property rights to contribute to innovation and promote public health. There are legal provisions for data protection for pharmaceuticals (Art. 39.3 of the Agreement on TRIPS). There are no legal provisions do not exist for patent extension. Laws do not exist for linkage between patent status and marketing authorization [11].

3.3 Manufacturing

There are 402 licensed pharmaceutical manufacturers (362 manufacturers of pharmaceutical products and 40 manufacturers of starting materials) in Argentina. Argentina has the capacity for:

The Research and Development for discovering new active substances	Yes
The production of pharmaceutical starting materials (APIs)	Yes
The production of formulations from pharmaceutical starting material	Yes
The repackaging of finished dosage form	Yes

[5] [12]

Section 4 - Regulation

This section covers a broad range of pharmaceutical regulatory policy, institutions and practices in Argentina

4.1 Regulatory Framework

In Argentina, there are legal provisions establishing the powers and responsibilities of the Medicines Regulatory Authority (MRA). The MRA is a semi-autonomous agency. The MRA has its own website. The URL address is http://www.anmat.gov.ar.

The MRA is involved in harmonization/collaboration initiatives. An assessment of the medicines regulatory system has been conducted in the last five year [8] [13].

The National Administration for Drugs, Food, and Medical Technology (ANMAT) has different areas for collaboration and harmonization:

- Domestic harmonization of internal laws and regulations enacted by the provinces.
- International harmonization through for example MERCOSUR (Southern Common Market) which is a venue for regulatory harmonization.

4.2 Marketing Authorization

In Argentina, legal provisions require a marketing authorization (registration) for all pharmaceutical products on the market. Explicit and publicly available criteria exist for assessing applications for marketing authorization of pharmaceutical products. In 2010, the number of pharmaceutical products registered in Argentina was 55,664. There are legal provisions requiring the MRA to make the list of registered pharmaceutical products publicly available regularly. This register is updated continuously. The updated list can be accessed through http://www.anmat.gov.ar. Medicines are registered by their INN (International Non-proprietary Names) or Brand name + INN. Legal provisions require a fee to be paid for Medicines Market Authorization (registration) based on applications [13] [14].

4.3 Regulatory Inspection

In Argentina, legal provisions exist allowing for appointment of government pharmaceutical inspectors [15]. The Regulatory Authority has 45 inspectors. Thirty-two are assigned to Good Manufacturing Practices (GMP) inspections, 3 to Good Distribution Practics (GDP) and 10 to marketing surveillance inspections. Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed [16]. Legal provisions exist requiring inspection to be performed. Inspection is a pre-requisite for licensing facilities [17].

4.4 Import Control

Legal provisions exist requiring authorization to import medicines [18]. Laws exist that allow the sampling of imported products for testing [19]. Legal provisions exist requiring importation of medicines through authorized ports of entry [20].

4.5 Licensing

In Argentina, legal provisions exist requiring manufacturers to be licensed [21]. Legal provisions exist requiring manufacturers to comply with Good Manufacturing Practices (GMP). Good Manufacturing Practices are published by the government [22]. Legal provisions exist requiring importers, wholesalers and distributers to be licensed [23] [24]. Legal provisions exist requiring wholesalers and distributors to comply with Good Distributing Practices [25]. Good Distribution Practices are published by the government. Legal provisions exist requiring pharmacists to be registered. Legal provisions exist requiring private and public pharmacies to be licensed. Argentina does not have public pharmacies with the same characteristics as private pharmacies. Hospital pharmacies, which are public, must meet quality standards. There are 24 provinces, which have the right to regulate whether the Good Pharmacy Practice guidelines are published or not. Therefore some jurisdictions publish them and others do not [13].

4.6 Market Control and Quality Control

In Argentina, legal provisions exist for controlling the pharmaceutical market [26]. The National Institute of medicines (INAME) is a National Control Laboratory for quality control testing of medicines. Samples are collected by government inspectors for undertaking post-marketing surveillance testing [27] [13].

4.7 Medicines Advertising and Promotion

In Argentina, legal provisions exist to control the promotion and/or advertising of prescription medicines. The government is responsible for regulating promotion and/or advertising of medicines. Legal provisions prohibit direct advertising of prescription medicines to the public. There are no legal provisions requiring a pre-approval for medicines advertisements and promotional materials. Guidelines and Regulations exist for advertising and promotion of non-prescription medicines. There is national code of conduct concerning advertising and promotion of medicines by marketing authorization holders. The code of conduct applies to both domestic and multinational manufacturers. Adherence to it is not voluntary. The code contains a formal process for complaints and sanctions. A list of the complaints and sanctions for the last two years is not publicly available [13].

4.8 Clinical Trials

In Argentina, legal provisions exist requiring authorization for conducting Clinical Trials by the MRA [29]. Laws require the agreement by an ethics committee or institutional review board of the Clinical Trials to be performed [13] [30].

4.9 Controlled Medicines

Argentina is signatory to the:

- Single Convention on Narcotic Drugs, 1961
- 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961
- Convention on Psychotropic Substances 1971
- United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988

Laws exist for the control of narcotic and psychotropic substances, and precursors. The annual consumption of morphine is 9.4 mg/capita [13] [31] [32].

4.10 Pharmacovigilance

In Argentina, there are no legal provisions in the Medicines Act that provide for pharmacovigilance activities as part of the MRA mandate. Legal provisions exist requiring the Marketing Authorization holder to continuously monitor the safety of their products and report to the MRA. In intensive surveillance programs for some drugs, active participation by doctors is sought. It is difficult to control this because ANMAT does not regulate the practice.
Laws about monitoring Adverse Drug Reactions (ADR) exist in Argentina. A national Pharmacovigilance centre linked to the MRA exists in Argentina. The Pharmacovigilance centre has 14 full-time staff members (four physicians, seven pharmacists, two secretaries and an administrative worker). It has published at least one analysis report in the previous two years and it also publishes an ADR bulletin. An official standardized form for reporting ADRs is used in Argentina. A national ADR database exists in Argentina. In the past 2 years, 500 ADR reports are sent to the WHO database in Uppsala. ADRs are not monitored in at least one public health program (example TB, HIV, AIDS) [13] [33] [34].

Section 5 - Medicines Financing

In this section, information is provided on the structure of user fees for medicines and on the existence of public programmes providing free medicines. Policies and regulations in place that affect the prices of medicines (e.g. price control and taxes) are presented.

5.1 Medicines Coverage and Exemptions

In Argentina, public programmes exist providing free medicines to:

Patients who cannot afford them	Yes
Children under 5	Yes
Pregnant women	Yes
Elderly persons	Yes

Public programmes exist providing free medicines for:

All diseases	No
Any non-communicable diseases	Yes
Malaria	Yes
Tuberculosis	Yes
Sexually transmitted diseases	Yes
HIV/AIDS	Yes
EPI Vaccines for children (expanded programme of immunization)	Yes

Public medicine programmes:
- The Federal Ministry of Health has a program to supply ambulatory drugs at no cost (REMEDIAR Program).
- Some provinces have diabetes programs that provide drugs. In turn, the REMEDIAR Program provides some drugs to treat chronic diseases such as diabetes, hypertension, asthma, epilepsy, gastritis, hypothyroidism, and arthritis.
- The HIV/AIDS program provides antiretroviral drugs and drugs for opportunistic diseases to all people who need them.
- The Oncology Drug Bank only provides drugs to patients who cannot pay for them.
- The provinces provide free of charge all drugs used by public hospital in-patients.
- Vaccines are distributed free of charge in primary health care centers. Note that in Argentina not only are vaccines provided free of charge, but all people (regardless of ability to pay) use this service.

A public health service, public health insurance, social insurance or other sickness fund provides at least partial medicines coverage. It provides coverage for medicines that are on the Essential Medicines List (EML) for inpatients and outpatients. The public sector provides all the drugs on the different essential drugs lists. In addition, in-patients are given all the drugs they need regardless of whether or not they are on the essential drugs list. The greatest problems are availability and logistics.

Argentina has different health subsystems, such as social security and private medical services. Social security membership is mandatory for employers and employees and the private service is voluntary (prepaid medical pocket expenditures of households, businesses, etc). In the case of social security (national or provincial) drug coverage is included in whole or in part through membership fees depending on the insurance and the kind of drug.
There is a rule "Governing Mandatory Health Program" that regulates at the national level the coverage compulsory minimum that should be the responsibility of the Agents of Health Insurance.

Private health insurance schemes provide medicines coverage. They are required to provide at least partial coverage for medicines that are on the EML. Private insurance systems, both prepaid and national social welfare programs, should cover the drugs listed on the PMO (Compulsory Medical Program). Coverage is 40% in general and 70 and 100% for chronic drugs [5].

5.2 Patients Fees and Copayments

In the health system of Argentina, at the point of delivery, there are no copayments/fee requirements for consultations and medicines. Revenue from fees or from the sale of medicines is not used to pay the salaries or supplement the income of public health personnel in the same facility [5].

5.3 Pricing Regulation for the Private Sector

In Argentina, there are no legal or regulatory provisions affecting pricing of medicines. The government runs an active national medicines price monitoring system for retail prices. The legal regulations in place establish freedom of pricing. Prices are regulated by the free play of supply and demand on the market. There are some voluntary pricing agreements between government and industry (http:/www.sssalud.gov.ar/index/index.php?cat=beneficiarios&opc=pap). The Ministry of Health produces the Average Drug Price Index (IPPM) and an index of weighted prices based on the REMEDIAR Program's essential drugs list. Both indices are updated monthly to monitor drug prices [5].

5.4 Duties and Taxes on Pharmaceuticals (Market)

There are duties on imported raw materials and imported finished products. Some raw materials and imported pharmaceutical products are tax exempt; these are listed in Decree 732. There is value-added tax (VAT) on pharmaceuticals. The VAT, however, is not levied on all stages of the distribution chain, but only at the manufacturing or importation stage. All pharmaceutical products are taxed by the usual VAT rate of 21% [35] [36].

Section 6 - Pharmaceutical procurement and distribution in the public sector

This section provides a short overview on the procurement and distribution of pharmaceuticals in the public sector of Argentina.

6.1 Public Sector Procurement

The public sector procurement in Argentina is centralized and decentralized. Drug provision in Argentina is centralized in the national programs (REMEDIAR) mentioned in section 5.1. In turn, since the provinces have autonomy over health decisions, they provide drugs through their own programs; for example, Buenos Aires province has a Drug Policy Bureau that conducts programs for high-cost drugs and drugs for long-term treatment. In addition, most public hospitals are decentralized at the provincial level, meaning that drug provision by providers is the responsibility of the provinces or municipals. The public sector procurement is centralized under the responsibility of a procurement agency which is a part of the MoH.

The public sector tender bids are publicly available (http:/www.msal.gov.ar/htm/site/lista_licitaciones.asp). Public sector awards are not publicly available. There is free access for adjudications by consultation, but they are not available on a web page in the same way that bids are; they can be consulted on the Internet by the resolution that granted it. The REMEDIAR Program is in the process of changing its web page and will publish both bids and awards. Procurements are not based on prequalification of suppliers [37]

The REMEDIAR Program, which has Inter-American Development Bank (IDB) funding, must comply with the Bank's quality requirements. Both this and other programs use the quality requirements of ANMAT.

6.2 Public Sector Distribution

The government supply system department in Argentina has a Central Medical Store at a National Level. Drugs for REMEDIAR are placed in a central warehouse from where they are distributed directly to the selected primary health care centers in the country. The DSyETS (The Bureau for HIV/AIDS and STDs) reported that, once drugs are adjudicated, there are two modalities for distribution:

1. The laboratories that are successful bidders make deliveries to national Ministry of Health storage facilities, from where drugs are distributed monthly to the provinces.
2. The drugs remain in the hands of the successful bidders and are distributed directly to the provinces and/or hospitals.

There are 24 public warehouses in the secondary tier of the public sector distribution (one per province). There are national guidelines on Good Distribution Practices (GDP). There is a licensing authority that issues GDP licenses. In the case of the provinces, the enforcement authority is the province and not the nation. The licensing authority does not accredit public distribution facilities. A list of GDP certified wholesalers and distributors exist in the public sector. Specific operational procedure exists for handling requests for authorization of distribution of immunobiological products prepared in Public Drug Production Laboratories and not registered in the Registry of Medicinal Preparations [37] [38].

6.3 Private Sector Distribution

Legal provisions exist for licensing wholesalers and distributors in the private sector of Argentina. The legal provisions correspond to the good drug storage, distribution, and transportation practices between provinces and the MERCOSUR area. A list of GDP certified wholesalers and distributors exists in the private sector [37] [38].

Section 7 - Selection and rational use of medicines

This section presents the structures and policies that are in place in Argentina for selection of essential medicines and promotion of rational drug use.

7.1 National Structures

National Standard Treatment Guidelines (STGs) for the most common illnesses are produced/endorsed by the MoH in Argentina. The national STGs have been updated in 2010. They cover primary care, secondary care and paediatric conditions. A National Essential Medicines List (EML) exists in Argentina. The EML was lastly updated in 2010. There is a written process for selecting medicines on the EML.

There are several essential drugs lists in Argentina. The drugs on the list for the free drug provision programs are intrinsically essential and for this reason the government chooses to provide them free of charge. These are:

- REMEDIAR Programs: 37 active ingredients, available in 54 formulations. The list is available at www.remediar.gov.ar (go to *botiquín*> *vademecum*).
- The Bureau of AIDS and STDs: 20 active ingredients (antiretrovirals) in 34 formulations. There are also 37 non-antiretroviral active ingredients (for opportunistic diseases) in 47 formulations.
- There is also an agreed essential drugs list in the MERCOSUR area, which is subject to change and is periodically updated.
- Finally, there are drug lists for the Compulsory Medical Program (PMO) for the private sector (prepaid) and national social welfare programs and the drug formulary list for provincial social welfare programs.

There is a public or independently funded national medicines information centre providing information on medicines to prescribers, dispensers and

consumers. Public education campaigns on rational medicine use topics have been conducted in the last two years. The campaigns are limited to the work of the REMEDIAR Program and are conducted through pamphlets and brochures (leaflets/fliers) sent to primary health care centers with rational drug use (RDU) recommendations for the public. No survey on rational use of medicines has been conducted in the previous two years. The REMEDIAR Program did some drug usage studies in 2007, together with *Salud Investiga*, another Ministry of Health program.

There is a national programme or committee, involving government, civil society, and professional bodies, to monitor and promote rational use of medicines. A written National Strategy to contain antimicrobial resistance exists. It has been updated in 2000 [8] [37] [39].

7.2 Prescribing

Legal provisions in Argentina exist to govern the licensing and prescribing practices of prescribers. Legal provisions exist to restrict dispensing by prescribers. There are no regulations requiring hospitals to organize/develop Drug and Therapeutics Committees (DTCs).

The core medical training curriculum includes components on:

The concept of EML	Yes
Use of STGS	Yes
Pharmacovigilance	Yes
Problem based pharmacotherapy	Yes

The core nursing training curriculum includes components on:

The concept of EML	Yes
Use of STGS	Yes
Pharmacovigilance	Yes

The core paramedical staff training curriculum includes components on:

The concept of EML	Yes
Use of STGS	Yes
Pharmacovigilance	Yes

Mandatory continuing education that includes pharmaceutical issues is not required for doctors, nurses and paramedical staff. Prescribing by INN name is obligatory in the public and private sector [6] [8] [40].

7.3 Dispensing

Legal provisions in Argentina exist to govern dispensing practices of pharmaceutical personnel. The core pharmacist training curriculum includes components on

The concept of EML	Yes
Use of STGs	Yes
Drug information	Yes
Clinical Pharmacy	Yes
Medicine Supply Management	Yes

Mandatory continuing education that includes pharmaceutical issues is not required for pharmacists.

Substitution of generic equivalents at the point of dispensing is allowed in public and private sector facilities. Antibiotics and injectable medicines are not sold over-the-counter without a prescription [6] [8].

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- **Law 16463 and Decree 150/1992** (question 2, 4.2).
- **ANMAT Resolution 5755/1996** (22 November 1996). Medicinal preparations. Registry. Implementing regulations for the handling and processing of applications for registration in the registry of medicinal preparations covered by articles 3, 4, and 5 of Decree 150/92 (question 2, 4.2). http://www.infoleg.gov.ar/infolegInternet/verNorma.do?id=41808
- **ANMAT Resolution 6897/2000** (29 November 2000). Medicinal preparations. Registration data - Evaluation of information (question 2, 4.2). http://www.infoleg.gov.ar/infolegInternet/verNorma.do?id=65344
- **ANMAT Resolution 3595/2004** (18 June 2004). Medicinal preparations. Amendment to Provision 6897/2000, establishing that the head of the registry should request technical inspection prior to marketing of medicinal preparations (question 2, 4.2). http://www.infoleg.gov.ar/infolegInternet/verNorma.do?id=96031

Regulatory inspection laws and decrees applicable in Argentina [15-17]:

[15] Law 16463 Art. 16; Decree 9763/94 Art. 1; Decree 1490/92 Art. 4 (delegation of authority); Resolution 1930/95 Arts. 5, 7, 9, and 10. Decree 341/92 Art. 3 Resolution 315/95. Available at: www.infoleg.gov.ar, 03-08-2010.

[16] Law 16463 Art. 16; Decree 9763 Art. 1; Resolution 1930/95 Arts. 5, 7, 9, and 10; Decree 341/92 Art. 3.

[17] Law 16463 Arts. 1 and 2; Decree 1490/92 Art. 3 (which gives ANMAT its authority); Resolution 2850/94 Annex II Actions of the Inspections Department (p. 16/71); Administrative Decision 22/03 Annex 2 Actions of INAME item 6 (empowers INAME to inspect establishments); Decree 150/92 Chapter II Art. 3; Resolution 2123/05.

Laws and decrees on import control applicable in Argentina [18-20]:

[18] Article 1 Resolution 2723/97 updated by Resolution 6607/05).

[19] Decree 9763/64 Article 38; Law 16463 Article 13; and Resolution 1930/95 Article 9.

[20] Resolution 6607/05, Resolution 4712/08.

Laws and decrees on licensing applicable in Argentina [21-25]:

[21] Law 16463 Articles 1 and 2; Decree 9763/64 Art. 4. Then, resolutions for specific products: Resolution 508/94 (alcohol) Article 2 and Art. 5 Item 2; Resolution 1130/00 (gases) Chapter II Article 4 Item 1. Resolution 3409/99 (pharmacopeia products) Art. 1; Resolution 144/98 (phytotherapeuticals) Arts. 3 and 4; Resolution 2671/99 (regulations for phytotherapeuticals); Resolution 2476/03 (physiological solution for nebulization) Art. 1.

[22] Law 16463 Art. 2; Decree 9763/64 Art. 6.

[23] Law 16463 Articles 1 and 2.

[24] Articles 1 and 2 Law 16463 and Articles 1 and 2 Resolution 538/98, Article 1 Resolution 7439/99.

[25] Article 4 Resolution 7439/99 (for distributors) and Article 6 5054/09, Article 6 Joint Resolution 470/92 and Ministry of Economy and Public Works and Services (MEyOSP) 268 regulations for Decree 150/92.

Laws and decrees on market and quality control applicable in Argentina [26-27]:

[26] Based on Decree 1490/32.

[27] Decree 9763/64 Article 38, Law 16463- Article 13, and Resolution 1930/95 Article 9-Resolution 1164/00 Item 6 Annex B.

[28] *Medicines advertising laws and regulations applicable in Argentina:*

- Resolution 627 of 2007.
- Resolution 20/05 of 2005.
- Law 16463 of 1964.
- ANMAT Resolution No. 4980.

[29] Provision 5330/97 Chapter III- Suspension item 9 Resolution 1490/07- Provision 1310/09 (ANMAT adheres to the Ministerial Resolution 1490/09) is Not

delegated the authorization, corresponding to the years 1997, 2007 and 2009 respectively.

[30] Resolution 1490/07-Annex I, Chapter 3 item 3.3. Functions and operations of the Ethics Committee. Provision 5330/97 Title XI Provision 1310/09, corresponding to the years 1997, 2007 and 2009 respectively.

[31] Report of the International Narcotics Control. Vienna, International Narcotics Control Board, 2009. Available at: www.incb.org, 08-06-2010.

[32] *Laws on controlled medicines applicable in Argentina*:

- Law 19.303 http://www.infoleg.gov.ar/infolegInternet/verNorma.do?id=20966
- Law 17.818 http://www.infoleg.gov.ar/infolegInternet/verNorma.do?id=20883

[33] *Pharmacovigilance activities in the medical act are governed by the following laws:* an administrative decision functions of the DEM 03.22. Item 6 (actions). Resolution 706/93. Article 1 and 2 Provision Provision 7089/99 and 2552/95 153/06 935/00 FV FV intensive intensive provision.

[34] Pharmacovigilance, ANMAT (Medicine Regulatory Authority). Buenos Aires, Ministry of Health. Available at: http://www.anmat.gov.ar/vigilancia.asp, 03-08-2010.

[35] Dirección de Administración General

[36] Decree 732

[37] REMEDIAR. Available at: http://www.remediar.gov.ar/, 03-08-2010.

[38] *Public sector distribution resolutions applicable in Argentina:*

- Resolution 5037-Good Drug Storage, Distribution, and Transportation Practices;
- Resolution 3475- MERCOSUR good distribution practices (GDP) for drugs.
- Resolution 3475-GDP MERCOSUR
- Resolution 5037-GDP.
- Disposición DISP3475-GDPmercosur & DISP5037-GDP
- Resolution 1644-List of Distributors

[39] Administración Nacional de Laboratorios e Institutos de Salud. ANLIS. Available at: http://www.anlis.gov.ar/, 03-08-2010.

[40] *Laws and regulations applicable in Argentina regarding prescribing:*

- **Law 17,132** referred to the legal regimen of the practice of medicine, dentistry, and its collaboration activities. http://www.infoleg.gov.ar/infolegInternet/anexos/15000-19999/19429/norma.htm
- **Remedial Decree 282/2009:** http://www.infoleg.gov.ar/infolegInternet/resaltaranexos/150000-154999/152381/norma.htm
- **Law 25,649:** Promotion of the utilization of drugs by their generic name. Sanctioned: August 2002. http://www.infoleg.gov.ar/infolegInternet/anexos/75000-79999/77881/norma.htm
- **Law 26,529:** Law of patient rights http://www.infoleg.gov.ar/infolegInternet/anexos/160000-164999/160432/norma.htm

ANNEX

Survey Data

Respondents to the questionnaire:

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Patricio Leavy

Section 1 Health and Demographic data

1.01 Demographic and Socioeconomic Indicators

Core Questions

Population, total (,000)	40,518	2010	Insituto Nacional de Estadísticas y Censos
Population growth rate (Annual %)	0.91	2010	Insituto Nacional de Estadísticas y Censos
GDP growth (Annual %)	0.9	2009	Insituto Nacional de Estadísticas y Censos
GNI per capita (US$ current exchange rate)	7,200	2008	World Bank
Comments			

Supplementary questions

Population < 15 years (% of total population)	25.1	2010	Insituto Nacional de Estadísticas y Censos
Population > 60 years (% of total population)	14	2007	World Health Statistics
Urban population (% of total population)	67	2007	World Health Statistics
Fertility rate, total (Births per woman)	2.3	2010	Insituto Nacional de Estadísticas y Censos
Population living with less than $1/day (international PPP) (%)	4.5	2005	United Nations Statistics Division
Population living below nationally defined poverty line (%)	13.2	2009	Insituto Nacional de Estadísticas y Censos
Income share held by lowest 20% of the population (% of national income)	3.4	2005	World Bank
Adult literacy rate, 15+ years (% of total population)	97.6	2007	World Health Statistics
Comments			

1.02 Mortality and Causes of Death

Core questions

Life expectancy at birth for men (Years)	71.6	2010	Insituto Nacional de Estadísticas y Censos
Life expectancy at birth for women (Years)	79.1	2010	Insituto Nacional de Estadísticas y Censos
Infant mortality rate, between birth and age 1 (/1,000 live births)	12.5	2008	Direction of Statistics and Information in Health (DEIS)
Under 5 mortality rate (/1,000 live births)	14.5	2008	DEIS
Maternal mortality ratio (/100,000 live births)	40	2008	DEIS
Comments			

Supplementary questions			
Adult mortality rate for both sexes between 15 and 60 years (/1,000 population)	126	2007	WHS
Neonatal mortality rate (/1,000 live births)	8.3	2008	DEIS
Age-standardized mortality rate by non-communicable diseases (/100,000 population)	515	2004	WHS
Age-standardized mortality rate by cardiovascular diseases (/100,000 population)	199.15	2008	DEIS
Age-standardized mortality rate by cancer (/100,000 population)	138.27	2008	DEIS
Mortality rate for HIV/AIDS (/100,000 population)	18	2007	WHS
Mortality rate for tuberculosis (/100,000 population)	4	2007	WHS
Mortality rate for Malaria (/100,000 population)	0	2006	WHS
Comments			

Section 2 Health Services

2.01 Health Expenditures

Core Questions

General government annual expenditure on health (millions US$ average exchange rate)	13,217	2007	Dirección de Análisis de Gasto Público y Programas Sociales - Secretaría de Política Económica-MECON
General government annual expenditure on health (millions NCU)	41,104	2007	Dirección de Análisis de Gasto Público y Programas Sociales - Secretaría de Política Económica-MECON
Government annual expenditure on health as percentage of total government budget (% of total government budget)	13.9	2007	Dirección de Análisis de Gasto Público y Programas Sociales - Secretaría de Política Económica-MECON
Annual per capita government expenditure on health (US$ average exchange rate)	336	2007	Dirección de Análisis de Gasto Público y Programas Sociales - Secretaría de Política Económica-MECON
Annual per capita government expenditure on health (NCU)	1,044	2007	Dirección de Análisis de Gasto Público y Programas Sociales - Secretaría de Política Económica-MECON
Population covered by a public health service or public health insurance or social insurance, or other sickness funds (% of total population)	100	2010	DES
Annual growth rate of total pharmaceuticals market value (%)	25	2008 - 2009	INDEC

Supplementary Questions

Social security expenditure as % of government expenditure on health (% of government expenditure on health)	58.7	2007	DAGPyPS
Comments			

2.02 Health Personnel and Infrastructure

Core Questions

Total number of pharmacists licensed/registered to practice in your country	20,074	2010	DNRSyCSS
A strategic plan for pharmaceutical human resource development is in place in your country?	No	2010	DNRSyCSS

Total number of physicians	212,076	2010	DNRSyCSS
Total number of nursing and midwifery personnel	85,489	2010	DNRSyCSS
Total number of hospitals	3,311	2000	DEIS
Total number of hospitals bed	153,065	2000	DEIS
Total number of primary health care units and centres	6,456	2000	DEIS
Supplementary Questions			
Total number of pharmacists who graduated (first degree) in the past 2 years in your country	1,294	2007 - 2008	DNRSyCSS
Are there accreditation requirements for pharmacy schools?	No	2010	DNRSyCSS
Is the Pharmacy Curriculum regularly reviewed?	Yes	2010	DNRSyCSS
Comments			

Section 3 Policy issues

3.01 Policy Framework

Core Questions

National Health Policy exists. If yes, please write year of the most recent document in the "year" field.	Yes	2007	DES
National Medicines Policy official document exists. If yes, please write the year of the most recent document in the "year" field and attach document or provide URL below*	No	2010	DES
Group of policies addressing pharmaceuticals exist. Please attach document or provide URL below *	Yes	2007	DES
National Medicines Policy covers the following components:			
Selection of Essential Medicines	Yes		
Medicines Financing	Yes		
Medicines Pricing	No		
Medicines Procurement	Yes		
Medicines Distribution	Yes		
Medicines Regulation	Yes		
Pharmacovigilance	Yes		
Rational Use of Medicines	Yes		
Human Resource Development	Yes		
Research	Yes		
Monitoring and Evaluation	Yes		
Traditional Medicine	No		
National medicines policy implementation plan exists. If yes, please write year of the most recent document in the "year" field.	No	2010	DES
Access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution or national legislation?	No	2010	SPRyFS
There are official written guidelines on medicines donations.	Yes	2010	ANMAT
Is pharmaceutical policy implementation being regularly monitored/assessed?	Yes	2010	DES
Who is responsible for pharmaceutical policy monitoring?			
Is there a national good governance policy?	Yes	2010	DES
Multisectoral	No		
For the pharmaceutical sector	Yes	2010	DES

A policy is in place to manage and sanction conflict of interest issues in pharmaceutical affairs. Please attach document or provide URL below *	Yes	2010	SPRyFS
There is a formal code of conduct for public officials. Please attach document or provide URL below *	Yes	2010	SPRyFS
Is there a whistle-blowing mechanism allowing individuals to raise a concern about wrongdoing occurring in the pharmaceutical sector of your country (ombudsman)?	No	2010	DES
3.02 Intellectual Property Laws and Medicines **Core Questions**			
Country is a member of the World Trade Organization	Yes	2010	MoH
Legal provisions provide for granting of Patents on pharmaceuticals	Yes	2010	MoH
National Legislation has been modified to implement the TRIPS Agreement	Yes	2010	MoH
Current laws contain (TRIPS) flexibilities and safeguards	Yes	2010	MoH
Country is eligible for the transitional period to 2016	No	2010	MoH
Which of the following (TRIPS) flexibilities and safeguards are present in the national law?			
Compulsory licensing provisions that can be applied for reasons of public health	Yes	2010	MoH
Bolar exception	Yes	2010	MoH
Are parallel importing provisions present in the national law?	Yes	2010	MoH
The country is engaged in initiatives to strengthen capacity to manage and apply intellectual property rights to contribute to innovation and promote public health	Yes	2010	MoH
Are there legal provisions for data exclusivity for pharmaceuticals	Yes	2010	MoH
Legal provisions exist for patent extension	No	2010	MoH
Legal provisions exist for linkage between patent status and marketing authorization	No	2010	MoH
3.03 Manufacturing **Core Questions**			
Number of licensed pharmaceutical manufacturers in the country	402	2009	Legajos de inspectoría ANMAT
Country has manufacturing capacity for:		2010	DES
R&D to discover new active substances	Yes		

Production of pharmaceutical starting materials (APIs)	Yes		
Production of formulations from pharmaceutical starting material	Yes		
Repackaging of finished dosage forms	Yes		
Supplementary Questions			
Number of manufacturers that are GMP certified	402	2009	Legajos de inspectoría ANMAT

Section 4 Regulation			
4.01 Regulatory Framework **Core Questions**			
Are there legal provisions establishing the powers and responsibilities of the medicines regulatory authority?	Yes	2010	SPRyFS
Part of MOH	No		
Semi autonomous agency	Yes		
The MRA has its own website	Yes	2010	SPRyFS
- If yes, please provide MRA Web site address (URL)	www.anmat.gov.ar		
The MRA is involved in harmonization/ collaboration initiatives	Yes	2010	SPRyFS
An assessment of the medicines regulatory system has been conducted in the last five years.	No	2010	SPRyFS
Supplementary Questions			
Formal code of conduct exists for staff involved in medicines regulation	Yes	2010	SPRyFS
Medicines Regulatory Authority gets funds from regular budget of the government.	Yes	2010	SPRyFS
Medicines Regulatory Authority is funded from fees for services provided.	Yes	2010	SPRyFS
Medicines Regulatory Authority receives funds/support from other sources	Yes	2010	SPRyFS
Revenues derived from regulatory activities are kept with the regulatory authority	Yes	2010	SPRyFS
The Regulatory Authority is using a computerized information management system to store and retrieve information on registration, inspections, etc.	Yes	2010	SPRyFS
Comments			
4.02 Marketing Authorization (Registration) **Core Questions**			
Legal provisions require a marketing authorization (registration) for all pharmaceutical products on the market	Yes	2010	ANMAT
Explicit and publicly available criteria exist for assessing applications for marketing authorization of pharmaceutical products	Yes	2010	ANMAT
Number of pharmaceutical products registered in your country	55,664	2010	ANMAT
Legal provisions require the MRA to make publicly available the registered pharmaceutical with defined periodicity	Yes	2010	ANMAT
- If yes, please provide updated list or URL *	www.anmat.gov.ar		

Medicines are registered by their INN (International Non-proprietary Names) or Brand name + INN	Yes	2010	ANMAT
Legal provisions require paying a fee for Medicines Market Authorization (registration) applications	Yes	2010	ANMAT
Supplementary Questions			
Legal provisions require marketing authorization holders to provide information about variations to the existing marketing authorization	Yes	2010	ANMAT
Legal provisions require to publish the Summary Product Characteristics (SPCs) of the medicines registered	Yes	2010	ANMAT
Legal provisions require the establishment of an expert committee involved in the marketing authorization process	No	2010	ANMAT
Certificate for Pharmaceutical Products in accordance with the WHO Certification scheme is required as part of the marketing authorization application	No	2010	ANMAT
Legal provision require declaration of potential conflict of interests for the experts involved in the assessment and decision-making for registration	No	2010	ANMAT
Legal provisions allow applicants to appeal against MRAs decisions	No	2010	ANMAT
Registration fee - the amount per application for pharmaceutical product containing New Chemical Entity,NCE (US$)	2,308	2010	ANMAT
Registration fee - the Amount per application for a multisource pharmaceutical product (US$)	256	2010	ANMAT
Time limit for the assessment of a marketing authorization application (Months)	4	2010	ANMAT
Comments			
4.03 Regulatory Inspection **Core Questions**			
Legal provisions exist allowing for appointment of government pharmaceutical inspectors	Yes	2010	ANMAT
Does the Regulatory Authority have inspectors?	Yes	2010	ANMAT
If yes, how many?	45	2010	ANMAT
Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed	Yes	2010	ANMAT
Legal provisions exist requiring inspection to be performed	Yes	2010	ANMAT
Inspection is a pre-requisite for licensing of facilities	Yes	2010	ANMAT
Inspection requirements are the same for public and private facilities	Unknown	2010	ANMAT
4.04 Import Control **Core Questions**			
Legal provisions exist requiring authorization to import medicines	Yes	2010	ANMAT
Legal provisions exist allowing the sampling of imported products for testing	Yes	2010	ANMAT

Legal provisions exist requiring importation of medicines through authorized ports of entry	Yes	2010	ANMAT
Legal provisions exist allowing inspection of imported pharmaceutical products at the authorized port of entry	Unknown	2010	ANMAT
Comments			
4.05 Licensing **Core Questions**			
Legal provisions exist requiring manufacturers to be licensed If yes please provide documents below.	Yes	2010	ANMAT
Legal provisions exist requiring manufacturers to comply with Good manufacturing Practices (GMP)	Yes	2010	ANMAT
GMP requirements are published by the government. If yes, please provide reference or URL below *	Yes	2010	ANMAT
Legal provisions exist requiring importers to be licensed	Yes	2010	ANMAT
Legal provisions exist requiring wholesalers and distributors to be licensed	Yes	2010	ANMAT
Legal provisions exist requiring wholesalers and distributors to comply with Good Distributing Practices	Yes	2010	ANMAT
National Good Distribution Practice requirements are published by the government	Yes	2010	ANMAT
Legal provisions exist requiring pharmacists to be registered	Yes	2010	ANMAT
Legal provisions exists requiring private pharmacies to be licensed	Yes	2010	SPRyFS
Legal provision exist requiring public pharmacies to be licensed	Yes	2010	SPRyFS
National Good Pharmacy Practice Guidelines are published by the government	Unknown	2010	SPRyFS
Comments			
Supplementary Questions			
Legal provisions require the publication of different categories of all pharmaceutical facilities licensed	Unknown	2010	ANMAT
Comments			
4.06 Market Control and Quality Control **Core Questions**			
Legal Provisions for controlling the pharmaceutical market exist	Yes	2010	ANMAT
Does a laboratory exist in the country for Quality Control testing?	Yes	2010	ANMAT
Samples are collected by government inspectors for undertaking post-marketing surveillance testing	Yes	2010	ANMAT
Results of quality testing in past two years are publicly available	Unknown	2010	ANMAT
Comments			
4.07 Medicines Advertising and Promotion			

Core Questions			
Legal provisions exist to control the promotion and/or advertising of prescription medicines	Yes	2007	WHO Level I
Who is responsible for regulating, promotion and/or advertising of medicines? Please describe:	Governme nt		
Legal provisions prohibit direct advertising of prescription medicines to the public	Yes	2010	ANMAT
Legal provisions require a pre-approval for medicines advertisements and promotional materials	No	2010	ANMAT
Guidelines/Regulations exist for advertising and promotion of non-prescription medicines	Yes	2010	ANMAT
A national code of conduct exists concerning advertising and promotion of medicines by marketing authorization holders and is publicly available	Yes	2010	ANMAT
If yes, the code of conduct applies to domestic manufacturers only, multinational manufacturers only, or both	Both	2010	ANMAT
If yes, adherence to the code is voluntary	No	2010	ANMAT
If yes, the code contains a formal process for complaints and sanctions	Yes	2010	ANMAT
If yes, list of complaints and sanctions for the last two years is publicly available	No	2010	ANMAT
Comments			
4.08 Clinical trials **Core Questions**			
Legal provisions exist requiring authorization for conducting Clinical Trials by the MRA	Yes	2010	ANMAT
Legal provisions exist requiring the agreement by an ethics committee/ institutional review board of the Clinical Trials to be performed	Yes	2010	ANMAT
Legal provisions exist requiring registration of the clinical trials into international/national/regional registry	Unknown	2010	ANMAT
Comments			
Supplementary Questions			
Legal provisions exist for GMP compliance of investigational products	Unknown	2010	ANMAT
Legal provisions require sponsor, investigator to comply with Good Clinical Practices (GCP)	Unknown	2010	ANMAT
National GCP regulations are published by the Government.	Unknown	2010	ANMAT
Legal provisions permit inspection of facilities where clinical trials are performed	Unknown	2010	ANMAT
Comments			
4.09 Controlled Medicines **Core Questions**			
The country is a signatory to conventions:			
- Single Convention on Narcotic Drugs, 1961	Yes	2010	ANMAT

- The 1972 Protocol amending the Single Convention on - Narcotic Drugs, 1961	Yes	2009	Int. Narcotics Control Board INCB
- Convention on Psychotropic Substances 1971	Yes	2010	ANMAT
United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	Yes	2010	ANMAT
Laws for the control of narcotic and psychotropic substances, and precursors exist, If yes, please attach below *	Yes	2010	ANMAT
Annual consumption of Morphine (mg/capita)	9.4	2007	ANMAT
Comments			
Supplementary Questions			
The laws and regulations for the control of narcotic and psychotropic substances, and precursors has been reviewed by a WHO International Expert or Partner Organization to assess the balance between the prevention of abuse and access for medical need	No	2010	ANMAT
Annual consumption of Fentanyl (mg/capita)	0.08	2007	ANMAT
Annual consumption of Pethidine (mg/capita)	0.325	2007	ANMAT
Annual consumption of Oxycodone (mg/capita)	0.387	2007	INCB
Annual consumption of Phenobarbital (mg/capita)	146.6	2007	ANMAT
Annual consumption of Methadone (mg/capita)	0.079	2007	ANMAT
Comments			
4.10 Pharmacovigilance **Core Questions**			
There are legal provision in the Medicines Act that provides for pharmacovigilance activities as part of the MRA mandate	No	2010	ANMAT
Legal provisions exist requiring the Marketing Authorization holder to continuously monitor the safety of their products and report to the MRA	Yes	2010	ANMAT
Legal provisions about monitoring Adverse Drug Reactions (ADR) exist in your country	Yes	2010	ANMAT
A national Pharmacovigilance centre linked to the MRA exists in your country	Yes	2010	ANMAT
If a national pharmacovigilance centre exists in your country, how many staff does it employ full-time	14	2010	ANMAT
If a national pharmacovigilance center exists in your country, an analysis report has been published in the previous two years. Please attach document or provide URL below *	Yes	2010	ANMAT
If a national pharmacovigilance center exists in your country, it publishes an ADR bulletin	Yes	2010	ANMAT
An official standardized form for reporting ADRs is used in your country. If yes, please attach document below *	Yes	2010	ANMAT
A national Adverse Drug Reactions database exists in your country.	Yes	2010	ANMAT
Are ADR reports set to the WHO database in Uppsala?	Yes	2010	ANMAT

If yes, number of reports sent in the past two years	500	2010	ANMAT
ADRs are monitored in at least one public health program (for example TB, HIV, AIDS)?	No	2010	ANMAT
Comments			
Supplementary Questions			
How many ADR reports are in the database?	32,330	2010	ANMAT
How many reports have been submitted in the past two years?	9,560	2010	ANMAT
Feedback is provided to reporters	Yes	2010	ANMAT
The ADR database is computerized	Yes	2010	ANMAT
Medications errors (MEs) are reported.	Yes	2010	ANMAT
How many MEs are there in the ADRs database?	151	2010	ANMAT
There is a risk management plan presented as part of product dossier submitted for Marketing Authorization?	Yes	2010	ANMAT
In the past two years, who has reported ADRs?		2010	ANMAT
Doctors	Yes		
Nurses	Yes		
Pharmacists	Yes		
Consumers	Yes		
Pharmaceutical Companies	Yes		
Others, please specify whom	ODONTOLOGISTS		
Was there any regulatory decision based on local PV data in the last 2 years?	Yes	2010	ANMAT
Are there training courses in Pharmacovigilance?	Yes	2010	ANMAT
If yes, how many people have been trained in the past two years?	15	2010	ANMAT
Comments			

Section 5 Medicines Financing

5.01 Medicines Coverage and Exemptions

Core Questions

If a public program providing free medicines exists, medicines are available free-of-charge for:			
Patients who cannot afford them	Yes	2010	DES
Children under 5	Yes	2010	DES
Pregnant women	Yes	2010	DES
Elderly persons	Yes	2010	DES
If a public program providing some/all medicines free exists, the following types of medicines are free			
All diseases	No	2010	DES
Any non-communicable diseases	Yes	2010	DES
Malaria medicines	Yes	2010	DES
Tuberculosis medicines	Yes	2010	DES
Sexually transmitted diseases medicines	Yes	2010	DES
HIV/AIDS medicines	Yes	2010	DES
EPI vaccines	Yes	2010	DES
Does a public health service, public health insurance, social insurance or other sickness fund provides at least partial medicines coverage	Yes	2010	DES
Does it provide coverage for medicines that are on the EML for inpatients	Yes		
Does it provide coverage for medicines that are on the EML for outpatients	Yes		
Does it provide at least partial medicines coverage for inpatients	No		
Does it provide at least partial medicines coverage for outpatients	No		
Please describe/explain your answers for questions above			
Do private health insurance schemes provide any medicines coverage?	Yes	2010	DES
If yes, is it required to provide at least partial coverage for medicines that are on the EML?	Yes		
Comments			

5.02 Patients Fees and Copayments

Core Questions

In your health system, at the point of delivery, are there any copayment/fee requirements for consultations	No	2010	DES
In your health system, at the point of delivery, are there any copayment/fee requirements for medicines	No	2010	DES
Is revenue from fees or from the sale of medicines used to pay the salaries or supplement the income of public	No	2010	DES

health personnel in the same facility			
Please describe the patient fees and copayments system			
Comments			
5.03 Pricing Regulation for the Private Sector **Core Questions**			
Are there legal or regulatory provisions affecting pricing of medicines	No	2010	DES
If yes, are the provisions aimed at Manufacturers	No		
If yes, are the provisions aimed at Wholesalers	No		
If yes, are the provisions aimed at Retailers	No		
Please explain the positive answers above: (explain scope of provisions i.e generics vs. originator or subsets of medicines, EML etc.			
Government runs an active national medicines price monitoring system for retail prices	Yes	2010	DES
Regulations exists mandating that retail medicine price information should be publicly accessible	Unknown	2010	DES
Comments			
5.06 Duties and Taxes on Pharmaceuticals (Market) **Core Questions**			
There are duties on imported active pharmaceutical ingredients (APIs)	Yes	2010	DGA
There are duties on imported finished products	Yes	2010	DGA
VAT (value-added tax) or any other tax on pharmaceuticals	Yes	2010	HED
- If yes, please specify categories of pharmaceuticals on which the taxes are applied			
Comments			
Supplementary Questions			
Amount of duties on imported active pharmaceutical ingredients, APIs (%)	32	2010	DGA
Amount of duties on imported finished products (%)	32	2010	DGA
Amount of VAT on pharmaceutical products (%)	21	2010	HED
Comments			

Section 6 Pharm.procurement and distribution

6.01 Public Sector Procurement

Core Questions

Public sector procurement is		2010	GV
Decentralized	No		
Centralized and decentralized	Yes		
Please describe			
If public sector procurement is wholly or partially centralized, it is under the responsibility of a procurement agency which is:		2010	GV
Part of MoH	Yes		
Semi-Autonomous	No		
Autonomous	No		
A government procurement Agency which procures all public goods	No		
Public sector tenders bids documents are publicly available	Yes	2010	GV
Public sector awards are publicly available	No	2010	GV
Procurements are based on prequalification of suppliers	No	2010	GV
If yes, please describe how it works			
Comments			

Supplementary Questions

Is there a written public sector procurement policy? If yes, please write the year of approval in the "year" field.	No	2010	GV
Are there provisions giving priority in public procurement to goods produced by local manufacturers?	Yes	2010	GV
The key functions of the procurement unit and those of the tender committee are clearly separated	Yes	2010	GV
A process exists to ensure the quality of products procured	Yes	2010	Gv
If yes, the quality assurance process includes pre-qualification of products and suppliers	Yes		
If yes, explicit criteria and procedures exist for pre-qualification of suppliers	Yes		
If yes, a list of pre-qualified suppliers and products is publicly available	No		
List of samples tested during the procurement process and results of quality testing is available	No	2010	GV
Which of the following tender methods are used in public sector procurement:		2010	GV
National competitive tenders	Yes		
International competitive tenders	Yes		

Direct purchasing	Yes		
Comments			
6.02 Public Sector Distribution **Core Indicators**			
The government supply system department has a Central Medical Store at National Level	Yes	2010	GV
Number of public warehouses in the secondary tier of public distribution (State/Regional/Provincial)	24	2010	GV
There are national guidelines on Good Distribution Practices (GDP)	Yes	2010	GV
There is a licensing authority that issues GDP licenses	Yes	2010	GV
If a licensing authority exists, does it accredit public distribution facilities?	No	2010	GV
List of GDP certified warehouses in the public sector exists	No	2010	GV
List of GDP certified distributors in the public sector exists	No	2010	GV
Comments			
Supplementary Questions			
Which of the following processes at the Central Medical Store is in place		2010	GV
Forecasting of order quantities	No		
Requisition/Stock orders	No		
Preparation of picking/packing slips	Yes		
Reports of stock on hand	Yes		
Reports of outstanding order lines	Yes		
Expiry dates management	Yes		
Batch tracking	Yes		
Reports of products out of stock	Yes		
Percentage of selected medicines with at least one stock out in the past year (%)	4	2010	GV
Routine Procedure exists to track the expiry dates of medicines	Yes	2010	GV
The Public Central Medical Store is GDP certified by a licensing authority	Yes	2010	GV
The Public Central Medical Store is ISO certified	Yes	2010	GV
The second tier public warehouses are GDP certified by a licensing authority	Yes	2010	GV
The second tier public warehouses are ISO certified	Unknown	2010	GV
6.03 Private Sector Distribution **Core Questions**			
Legal provisions exist for licensing wholesalers in the private sector	Yes		
Legal provisions exist for licensing distributors in the private sector	Yes		
List of GDP certified wholesalers in the private sector	Yes		

exists			
List of GDP certified distributors in the private sector exists	Yes		
Comments			

Section 7 Selection and rational use

7.01 National Structures

Core Questions

National Standard Treatment Guidelines (STGs) for most common illnesses are produced/endorsed by the MoH. If yes, please insert year of last update of STGs in the "year" field	Yes	2010	SPRyFS
If yes, STG's are applied to Primary care. Please use the "year" field to write the year of last update of primary care STGs.	Yes	2010	SPRyFS
If yes, STG's are applied to Secondary (hospitals). Please use the "year" field to write the year of last update of secondary care STGs.	Yes	2010	SPRyFS
If yes, STG's are applied to Paediatric conditions. Please use the "year" field to write the year of last update of paediatric condition STGs.	Yes	2010	SPRyFS
National essential medicines list (EML) exists. If yes, please write year of last update of EML in the "year" field	Yes	2010	SPRyFS
If yes, number of medicines on the EML			
If yes, there is a written process for selecting medicines on the EML	Yes		
If yes, the EML is publicly available	Yes		
A public or independently funded national medicines information centre provides information on medicines to prescribers, dispensers and consumers	Yes	2010	SPRyFS
Public education campaigns on rational medicine use topics have been conducted in the previous two years	Yes	2010	GV
A survey on rational use of medicines has been conducted in the previous two years	No	2010	GV
A national programme or committee (involving government, civil society, and professional bodies) exists to monitor and promote rational use of medicines	Yes	2010	GV
A written National Strategy exists to contain antimicrobial resistance. If yes, please write year of last update of the strategy in the "year" field and attach document or provide URL below.	Yes	2000	ANLIS
Comments			

Supplementary Questions

The EML includes formulations specific for children	Yes	2010	SPRyFS
There are explicit documented criteria for selection of medicines in the EML	Yes	2010	SPRyFS
There is a formal committee or other equivalent structure for the selection of products on the national EML	Yes	2010	SPRyFS
If yes, provide the official documentation establishing the committee *			

If yes, conflict of interest declarations are required from members of national EML committee	Yes		
National medicines formulary exists	Yes	2010	SPRyFS
Is there a funded national inter-sectoral task force to coordinate the promotion of appropriate use of antimicrobials and prevention of spread of infection?	Yes	2010	ANLIS
A national reference laboratory/or any other institution has responsibility for coordinating epidemiological surveillance of antimicrobial resistance	Yes	2010	ANLIS
Comments			
7.02 Prescribing **Core Questions**			
Legal provisions exist to govern the licensing and prescribing practices of prescribers	Yes	2010	SPRyFS
Legal provisions exist to restrict dispensing by prescribers	Yes	2010	SPRyFS
Regulations require hospitals to organize/develop Drug and Therapeutics Committees (DTCs)	No	2010	SPRyFS
The core medical training curriculum includes components on:		2010	DNRSyCSS
Concept of EML	Yes		
Use fo STGs	Yes		
Pharmacovigilance	Yes		
Problem based pharmacotherapy	Yes		
The core nursing training curriculum includes components on:		2010	DNRSyCSS
Concept of EML	Yes		
Use of STGs	Yes		
Pharmacovigilance	Yes		
The core training curriculum for paramedical staff includes components on:		2010	DNRSyCSS
Concept of EML	Yes		
Use of STGs	Yes		
Pharmacovigilance	Yes		
Mandatory continuing education that includes pharmaceutical issues is required for Doctors	No	2010	DNRSyCSS
Mandatory continuing education that includes pharmaceutical issues is required for Nurses	No	2010	DNRSyCSS
Mandatory continuing education that includes pharmaceutical issues is required for Paramedical staff	No	2010	DNRSyCSS
Prescribing by INN name is obligatory in:			
Private sector	Yes	2010	SPRyFS
Public sector	Yes	2010	SPRyFS
Supplementary Questions			

A professional association code of conduct exists governing professional behavior of doctors	Yes	2010	SPRyFS
A professional association code of conduct exists governing professional behavior of nurses	Yes		
Comment			
7.03 Dispensing **Core Questions**			
Legal provisions exist to govern dispensing practices of pharmaceutical personnel	Yes	2010	SPRyFS
The basic pharmacist training curriculum includes components on:		2010	DNRSyCSS
Concept of EML	Yes		
Use of STGs	Yes		
Drug Information	Yes		
Clinical pharmacology	Yes		
Medicines supply management	Yes		
Mandatory continuing education tat includes rational use of medicines is required for pharmacists	No	2010	DNRSyCSS
Substitution of generic equivalents at the point of dispensing in public sector facilities is allowed	Yes	2010	SPRyFS
Substitution of generic equivalents at the point of dispensing in private sector facilities is allowed	Yes	2010	SPRyFS
Antibiotics are sold over-the-counter without a prescription	No	2010	SPRyFS
Injectable medicines are sold over-the-counter without a prescription	No	2010	SPRyFS
Comments			
Supplementary Questions			
A professional association code of conduct exists governing professional behavior of pharmacists	Yes	2010	SPRyFS
Are the following categories of staff prescribing prescription-only medicines at primary care level in the public sector?		2010	SPRyFS
Doctors	Yes		
Nurses	No		
Pharmacists	No		
Comments			