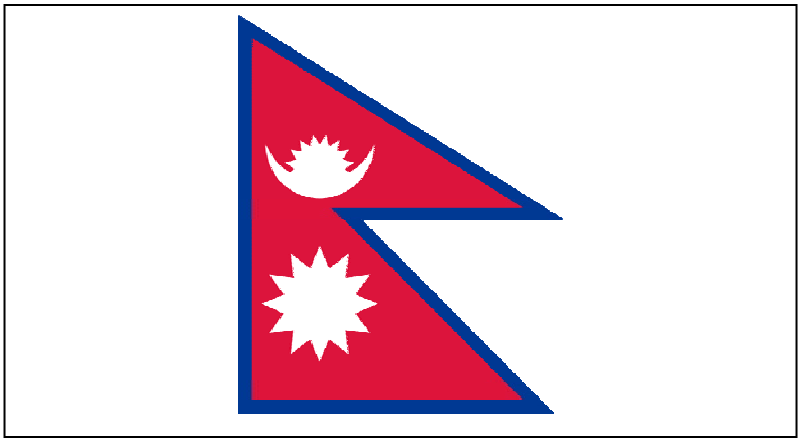
# NEPAL



# PHARMACEUTICAL COUNTRY PROFILE

# Nepal Pharmaceutical Country Profile

Published by Ministry of Health and Population in collaboration with
the World Health Organization

## September 27, 2011



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# Foreword

The 2011 Pharmaceutical Country Profile for Nepal has been produced by the Ministry of Health and Population, in collaboration with the World Health Organization.

This document contains information on existing socio-economic and health-related conditions, resources; as well as on regulatory structures, processes and outcomes relating to the pharmaceutical sector in Nepal. The compiled data comes from international sources (e.g. the World Health Statistics), surveys conducted in the previous years and country level information collected in 2011. 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 Health and Population, Government of Nepal, I wish to express my appreciation to Mr. Radha Raman Prasad , Department of Drug Administration; Mr. Bhupendra Bahadur Thapa, Ministry of Health and Population and Mr. Navin Prasad Shrestha from Pharma-Solution Concern for their contributions to the process of data collection and the development of this profile.

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

Name: Dr. Sudha Sharma

Function in the Ministry of Health and Population:

Secretary

Date: September 27, 2011

Signature: 

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## Introduction

This Pharmaceutical Country Profile provides data on existing socio-economic and health-related conditions, resources, regulatory structures, processes and outcomes relating to the pharmaceutical sector of Nepal. The aim of this document is to compile all relevant, existing information on the pharmaceutical sector and make it available to the public in a user-friendly format. In 2010, the country profiles project was piloted in 13 countries (http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index.html). During 2011, the World Health Organization has supported all WHO Member States to develop similar comprehensive pharmaceutical country profiles.

The information is categorized in 9 sections, namely: (1) Health and Demographic data, (2) Health Services, (3) Policy Issues, (4) Medicines Trade and Production (5) Medicines Regulation, (6) Medicines Financing, (7) Pharmaceutical procurement and distribution, (8) Selection and rational use, and (9) Household data/access. The indicators have been divided into two categories, namely "core" (most important) and "supplementary" (useful if available). This narrative profile is based on data derived from both the core and supplementary indicators. The tables in the annexes also present all data collected for each of the indicators in the original survey form. For each piece of information, the year and source of the data are indicated; these have been used to build the references in the profile and are also indicated in the tables. If key national documents are available on-line, links have been provided to the source documents so that users can easily access these documents.

The selection of indicators for the profiles has involved all technical units working in the Essential Medicines Department of the World Health Organization (WHO),

as well as experts from WHO Regional and Country Offices, Harvard Medical School, Oswaldo Cruz Foundation (known as Fiocruz), University of Utrecht, the Austrian Federal Institute for Health Care and representatives from 13 pilot countries.

Data collection in all 193 member states has been conducted using a user-friendly electronic questionnaire that included a comprehensive instruction manual and glossary. Countries were requested not to conduct any additional surveys, but only to enter the results from previous surveys and to provide centrally available information. To facilitate the work of national counterparts, the questionnaires were pre-filled at WHO HQ using all publicly-available data and before being sent out to each country by the WHO Regional Office. A coordinator was nominated for each of the member states. The coordinator for Nepal was Mr. Radha Raman Prasad.

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

This profile will be regularly updated by Department of Drug Administration. Comments, suggestions or corrections may be sent to:

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Madan Bhandari Path, Kathmandu
NEPAL.
e-mail : director@dda.gov.np

# Section 1 - Health and Demographic Data

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

## 1.1 Demographics and Socioeconomic Indicators

The total population of Nepal in 2010 was 28,043,744 with an annual population growth rate of 2.25%. The annual GDP growth rate is 3.53 % [1]. The GDP per capita was US$ 562 (at the current exchange rate[i]). Population below 15 years is 37 percent and above 60 years is 6 percent of the total population [2].Urban population is 17.7 percent of the total population [3]. Adult literacy rate (above 15 years) is 57.9 percent [3].

## 1.2 Mortality and Causes of Death

The life expectancy at birth is 63.6 and 64.5 years for men and women respectively [1]. The infant mortality rate (i.e. children under 1 year) is 46/1,000 live births and for children under the age of 5, the mortality rate is 54/1,000 live births [4]. The maternal mortality rate is 281/100,000 live births [5].

[i] The exchange rate for calculation for NCU (NPR) is 69.76 for I USD, which is consistent with the timing of the collection of related NHA data.

**Table 1: The top 10 diseases causing mortality in Nepal** [6]

| | Disease | Deaths per 10,000 | % of deaths |
|---|---|---|---|
| 1 | Cardiovascular Disorder | 20.2 | 21.0 |
| 2 | Injuries and Others | 7.6 | 7.9 |
| 3 | Perinatal Conditions | 7.2 | 7.5 |
| 4 | Malignant and other Neoplasms | 6.0 | 6.3 |
| 5 | Respiratory Disorders | 5.8 | 6.0 |
| 6 | Respiratory Infections | 4.7 | 4.9 |
| 7 | Tuberculosis | 4.1 | 4.3 |
| 8 | Digestive System Disorders | 3.8 | 4.0 |
| 9 | HIV/AIDS | 2.4 | 2.5 |
| 10 | a. Maternal Conditions<br>b. Vaccine Preventable Diseases | 1.9<br>1.9 | 2.0<br>2.0 |

**Table 2: The top 10 diseases causing morbidity in Nepal** [7]

| | Disease | Deaths per 10,000 | % of deaths |
|---|---|---|---|
| 1 | Gastritis (APD) | NA | NA |
| 2 | Intestinal Worms | NA | NA |
| 3 | Lower Respiratory Tract Infections | NA | NA |
| 4 | Headache | NA | NA |
| 5 | Upper Respiratory Infections | NA | NA |
| 6 | Fever | NA | NA |
| 7 | Impetigo/ Boils/ Furunculosis | NA | NA |
| 8 | Diarrhoea | NA | NA |
| 9 | Amoebic Dysentery/ Amoebiasis | NA | NA |
| 10 | Falls/ Injuries/ Fractures | NA | NA |

## Section 2 - Health Services

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

### 2.1 Health Expenditures

In Nepal, the total annual expenditure on health (THE) in 2008 was 39,944.15 million Nepalese Rupees (NPR) (US$ 69.76 million). The total annual health expenditure was 4.54 % of the GDP. The total annual expenditure on health per capita was 1,386.47 Nepalese Rupees (US$ 19.87 ) [8].

The general government[ii] health expenditure (GGHE) in 2008, as reflected in the national health accounts (NHA) was NPR 15,572.11million (US$ 223.22 million), that is, 38.98 % of the total expenditure on health. Annual per capita public expenditure on health is NPR 540.51 (US$ 7.75 [8]. The government annual expenditure on health represents 6.33 % of the total government budget. Private health expenditure covers the remaining 61.02 % of the total health expenditure.

Total pharmaceutical expenditure (TPE) in Nepal in 2008 was NPR 13,089 million (US$ 187.64 million), which is a per capita pharmaceutical expenditure of 485.41 NPR (US$ 6.96) [9]. The total pharmaceutical expenditure accounts for 1.60 % of the GDP and makes up 32.77 % of the total health expenditure (Figure 1). Public expenditure on pharmaceuticals represents 22.6 % of the total

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

expenditure on pharmaceuticals (Figure 2), this converts into a per capita public expenditure on pharmaceuticals of NPR 109.83 (US$ 1.57) [8].

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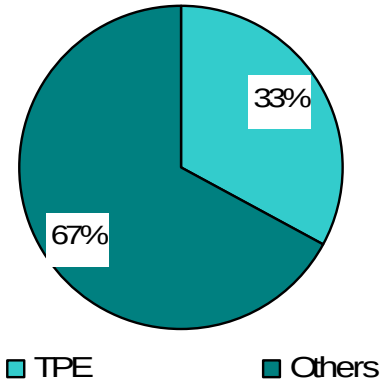
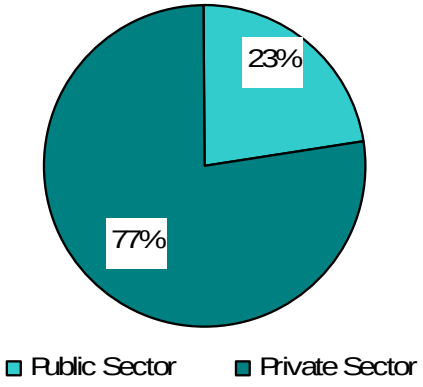
**FIGURE 1: Share of Total Pharmaceutical Expenditure as percentage of the Total Health Expenditure 2008. The THE in 2008 was 39,944.15 million NPR (US$ 572.59 million)**




[Sources: NHA 2008 and NPE 2011]

**FIGURE 2: Share of Total Pharmaceutical Expenditure by sector, 2008**




[Source: NPE 2011]

Total private expenditure on pharmaceuticals is NPR 10,062.24 million (US$ 144.24 million).

## 2.2 Health Personnel and Infrastructure

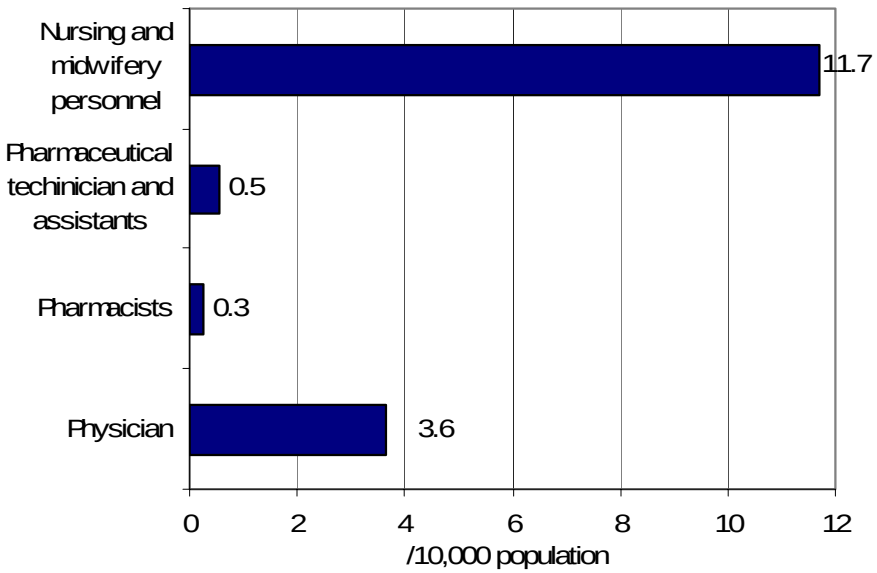
The health workforce is described in the table below and in Figure 3 and 4. At the end of December, 2010, there are 731 (0.261 /10,000) licensed pharmacists, of which 35 (0.013 /10,000) work in the public sector. There are 1,496 (0.533 /10,000) pharmaceutical technicians and assistants (in all sectors) [10]. There are approximately 2.05 as many pharmacy technicians as pharmacists.

There are 10,197 (3.64 /10,000) physicians (including dental surgeons) [11] and 32,846 (11.71 /10,000) nursing and midwifery personnel [12] in Nepal. The ratio of doctors to pharmacists is 1:0.072 and the ratio of doctors to nurses and midwifery personnel is 1:3.03.

**Table 3: Human resources for health in Nepal**

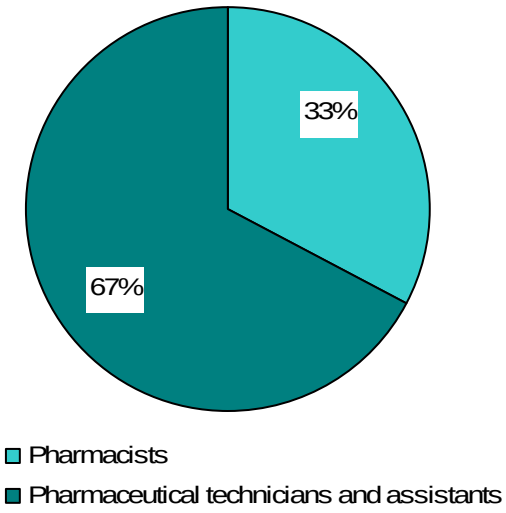
| Human Resource | Number (ratio/population) |
|---|---|
| Licensed pharmacists (all sectors) | 731 (0.261 /10,000) |
| Pharmacists in the public sector | 35 (0.0125/10,000) |
| Pharmaceutical technicians and assistants (all sectors) | 1,496 (0.533/10,000) |
| Physicians (all sectors) | 10,197 (3.64 /10,000) |
| Nursing and midwifery personnel (all sectors) | 32,846 (11.71 /10,000) |

**Figure 3: The density of the Health Workforce in Nepal (all sectors, 2010)**




(Sources: Concerned Councils, 2010)

**Figure 4: Distribution of Pharmaceutical Personnel, Nepal, 2010**




In Nepal, there is a strategic plan for human resource for health, which also includes pharmaceutical human resource development [13].

The health facility is described in Table 4. There are 295 hospitals and 25,366 hospital beds in Nepal. There are 4,029 primary health care units and centres and 12,709 licensed pharmacies.

**Table 4: Health centre and hospital statistics**

| Infrastructure | |
|---|---|
| Hospitals | 295 [14] |
| Hospital beds | 25,366 [14] |
| Primary health care units and centres | 4,029 [14] |
| Licensed pharmacies | 12,709 [15] |

## Section 3 - Policy Issues

This section addresses the main characteristics of the pharmaceutical policy in Nepal. The many components of a national pharmaceutical policy are taken from the WHO publication “How to develop and implement national drug policy” (http://apps.who.int/medicinedocs/en/d/Js2283e/). Information about the capacity for manufacturing medicines and the legal provisions governing patents is also provided.

### 3.1 Policy Framework

In Nepal, a National Health Policy (NHP) exists [16]. It was developed in 1991. For the implementation of National Health Policy 1991, Second Long Term Health Plan 1997 - 2017 was prepared [17]. However the first implementation plan came as Nepal Health Sector Program - Implementation Plan (NHSP-IP for 2004 - 2009) in October 2004 [18]. It emphasizes on increased coverage and raise the quality of essential healthcare services with special emphasis on improved access for poor and vulnerable groups. The outputs are classified in eight groups namely prioritised essential healthcare services, decentralised healthcare management, private and non-governmental sector development, sectoral management, financing and resource allocation, management of physical assets, human resource development and integrated management of information system & quality assurance policy. Nepal Health Sector Programme-II (NHSP-2) 2010 - 2015 has given top priority to essential healthcare services, encompassing family planning, safe motherhood, adolescence sexual and reproductive health, new born care, child health, communicable and non-communicable diseases, oral health, environmental health and curative services. It also emphasizes on emergency and disaster management and Ayurvedic and alternate system of medicine [19].

An official National Medicines Policy document exists in Nepal [20]. It was developed in 1995.

A NMP implementation plan does not exist. Policies addressing pharmaceuticals exists, as detailed in Table 5. Pharmaceutical policy implementation is regularly monitored/assessed by Ministry of Health and Population.

**Table 5: The NMP covers**

| Aspect of policy | Covered |
|---|---|
| Selection of essential medicines | Yes |
| Medicines financing | No |
| Medicines pricing | Yes |
| Medicines Procurement | Yes |
| Medicines Distribution | Yes |
| Medicines Regulation | Yes |
| Pharmacovigilance | No |
| Rational use of medicines | Yes |
| Human Resource Development | Yes |
| Research | Yes |
| Monitoring and evaluation | Yes |
| Traditional Medicine | Yes |

A policy relating to clinical laboratories does not exist. An associated National clinical laboratory policy implementation plan does not exist. Access to essential medicines/technologies as part of the fulfillment of the right to health, is recognized in the constitution [21]. There are official written guidelines on medicines donations [22].

There is a national good governance Act in Nepal [23].

This Good Governance Act is multisectoral. Concerned Ministry at the central level and various government offices at central, regional, zonal, district and local

level are responsible for implementing this Act. Good Governance Regulations [24] facilitates for the implementation of the Act.

A policy is not in place to manage and sanction conflict of interest issues in pharmaceutical affairs. There is an associated formal code of conduct for public officials [25]. A whistle-blowing mechanism that allows individuals to raise concerns about wrongdoing occurring in the pharmaceutical sector of Nepal exists [26]. Consumer Protection Act is for protecting consumers from the irregularities concerning the quality, quantity and prices of consumer goods and services. Medicine is listed among the consumer goods. The regulations and the guidelines under this Act has provision to constitute committees with representation of consumer associations and local people. These committees can monitor the market and individual consumer can put their concerns to the committees. If some harm is done, they can claim for compensation. The legal documents are available at www.lawcommission.gov.np.

# Section 4 – Medicines Trade and Production

## 4.1 Intellectual Property Laws and Medicines

Nepal is a member of the World Trade Organization [27]. Legal provisions granting patents to manufacturers exist as per the Patent, Design and Trademark Act, 1965 [28]. Patent is initially granted for seven years, and can be renewed twice, each for seven years period. These cover pharmaceuticals, laboratory supplies, medical supplies and medical equipment. Intellectual Property Rights are managed and enforced by Department of Industry; the webpage is www.ip.np.wipo/ and www.doind.gov.np.

National Legislation has not been modified to implement the TRIPS Agreement and does not contain TRIPS-specific flexibilities and safeguards, presented in Table 6. Nepal is eligible for the transitional period to 2016.

**Table 6: TRIPS flexibilities and safeguards are present in the national law**

| Flexibility and safeguards | Included |
|---|---|
| Compulsory licensing provisions that can be applied for reasons of public health | No |
| Bolar exceptions[iii] | No |
| Parallel importing provisions | No |

[iii] Many countries use this provision of the TRIPS Agreement to advance science and technology. They allow researchers to use a patented invention for research, in order to understand the invention more fully.
In addition, some countries allow manufacturers of generic drugs to use the patented invention to obtain marketing approval (for example from public health authorities) without the patent owner's permission and before the patent protection expires. The generic producers can then market their versions as soon as the patent expires. This provision is sometimes called the "regulatory exception" or "Bolar" provision.
*Article 30:* This has been upheld as conforming with the TRIPS Agreement in a WTO dispute ruling. In its report adopted on 7 April 2000, a WTO dispute settlement panel said Canadian law conforms with the TRIPS Agreement in allowing manufacturers to do this. (The case was titled "Canada - Patent Protection for Pharmaceutical Products")
*[In: WTO OMC Fact sheet: TRIPS and pharmaceutical patents, can be found on line at: http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf]*

The country is not engaged in capacity-strengthening initiatives to manage and apply Intellectual Property Rights in order to contribute to innovation and promote public health.

Nepal is in process of enacting “Industrial Property Protection Act” to replace the Patent, Design and Trademark Act, 2022 (1965). However, being eligible for the transitional period till 2016, the draft Act is under discussion so that all flexibilities provided by TRIPS Agreement and Doha Development Agenda could be fully utilised. Regarding linkage between patent status and marketing authorization, Drug Act [29] mentions that the right to registration of patent will be as per prevailing Act, but does not mention any linkage of patent status.

### 4.2 Manufacturing

There are 87 licensed pharmaceutical manufacturers in Nepal, out of which 41 manufacture modern medicine, 7 veterinary products and 37 manufacture herbal preparations [15]. Manufacturing capabilities are presented in Table 7 below.

**Table 7: Nepal manufacturing capabilities**

| Manufacturing capabilities | |
|---|---|
| Research and Development for discovering new active substances | No |
| Production of pharmaceutical starting materials (APIs) | No |
| The production of formulations from pharmaceutical starting material | Yes |
| The repackaging of finished dosage forms | Yes |

In 2008, domestic manufacturers held 42 % of the market share by value produced [9].

## Section 5 – Medicines Regulation

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

### 5.1 Regulatory Framework

In Nepal, there are legal provisions establishing the powers and responsibilities of the Medicines Regulatory Authority (MRA). Department of Drug Administration (DDA) is the medicine regulatory authority.

The MRA is a part of the MoHP with a number of functions outlined in Table 8. MRA (Department of Drug Administration) was established as per the provision in Drug Act 1978 [29] and is functional since 1979. The MRA has its own website, for which the URL address is http://www.dda.gov.np.

**Table 8: Functions of the national MRA**

| Function | |
|---|---|
| Marketing authorisation / registration | Yes |
| Inspection | Yes |
| Import control | Yes |
| Licensing | Yes |
| Market control | Yes |
| Quality control | Yes |
| Medicines advertising and promotion | Yes |
| Clinical trials control | Yes |
| Pharmacovigilance | No |
| Other [describe] | |

As of 2011, there were 79 permanent staffs working for the MRA. The MRA receives external technical assistance only from WHO in HRD and some other identified technical areas to support its activities. The MRA is not involved in harmonization/collaboration initiatives. An assessment of the medicines regulatory system has not been conducted in the last five year. Funding for the MRA is provided through the regular government budget. The Regulatory Authority does not retain revenues derived from regulatory activities. This body utilizes a computerized information management system to store and retrieve information on processes that include registrations, inspection etc.

### 5.2 Marketing Authorization (Registration)

In Nepal, legal provisions require marketing authorization (registration) for all pharmaceutical products on the market. Mutual recognitions mechanisms are not in place. Explicit and publicly available criteria exist for assessing applications for marketing authorization of pharmaceutical products [30]. In 2011, there were 10,316 pharmaceutical products registered in Nepal [15]. There are not legal provisions requiring the MRA to make the list of registered pharmaceutical products publicly available and update it regularly. Medicines are always 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 [30].

### 5.3 Regulatory Inspection

In Nepal, legal provisions exist allowing for appointment of government pharmaceutical inspectors [29, 31]. Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed; such inspections are required by law and are not a pre-requisite for the licensing of public and private facilities. Where inspections are legal requirements, these are the same for public and private facilities [31]. Inspections are carried out on a number of entities, outlined in Table 9.

**Table 9: Local entities inspected for regulatory compliance**

| Entity | Inspection | Frequency |
|---|---|---|
| Local manufacturers | Yes | Not fixed |
| Private wholesalers | Yes | Not fixed |
| Retail distributors | Yes | Not fixed |
| Public pharmacies and stores | Yes | Not fixed |
| Pharmacies and dispensing points if health facilities | Yes | Not fixed |

## 5.4 Import Control

Legal provisions exist requiring authorization to import medicines [29]. Laws exist that allow the sampling of imported products for testing.

Legal provisions exist requiring importation of medicines through authorized ports of entry. Regulations or laws exist to allow for inspection of imported pharmaceutical products at authorized ports of entry [31].

## 5.5 Licensing

In Nepal, legal provisions exist requiring manufacturers to be licensed [29]. Legal provisions exist requiring manufacturers (both domestic and international) to comply with Good Manufacturing Practices (GMP) [32]. Good Manufacturing Practices are published by the government.

Legal provisions exist requiring importers/wholesalers/distributers to be licensed [30]. Legal provisions do not exist requiring wholesalers and distributors to comply with Good Distribution Practices.

**Table 10: Legal provisions pertaining to licensing**

| Entity requiring licensing | |
|---|---|
| Importers | Yes |
| Wholesalers | Yes |
| Distributors | Yes |

Good Distribution Practices are not published by the government.

Legal provisions exist requiring pharmacists to be registered [33]. Legal provisions exists requiring private/public pharmacies to be licensed [29, 30].

National Good Pharmacy Practice Guidelines are not published by the government. By law, a list of all licensed pharmaceutical facilities is not required to be published.

## 5.6 Market Control and Quality Control

In Nepal, legal provisions exist for controlling the pharmaceutical market [29, 30].

A laboratory exists in Nepal for Quality Control testing. The laboratory (National Medicines Laboratory), established as per the provision of Drug Act [29], is a functional part of the MRA.

Existing national laboratory facilities have not been accepted for collaboration with the WHO pre-qualification Programme. Medicines are tested for a number of reasons, summarised in Table 11.

**Table 11: Reason for medicines testing**

| Medicines tested: | |
|---|---|
| For quality monitoring in the public sector[iv] | Yes |
| For quality monitoring in the private sector[v] | Yes |
| When there are complaints or problem reports | Yes |
| For product registration | Yes |
| For public procurement prequalification | No |
| For public program products prior to acceptance and/or distribution | Yes |

[iv] Routine sampling in pharmacy stores and health facilities
[v] Routine sampling in retail outlets

Samples are collected by government inspectors for undertaking post-marketing surveillance testing.

In the past 2 years, 1,229 samples were taken for quality control testing. Of the samples tested, 47 failed to meet the quality standards [15]. The results are not publicly available.

### 5.7 Medicines Advertising and Promotion

In Nepal, legal provisions exist to control the promotion and/or advertising of prescription medicines [29, 30]. Department of Drug Administration is responsible for regulating promotion and/or advertising of medicines. Legal provisions prohibit direct advertising of prescription medicines to the public and pre-approval for medicines advertisements and promotional materials is required. Regulations exist for advertising and promotion of non-prescription medicines. There is not national code of conduct concerning advertising and promotion of medicines by marketing authorization holders.

### 5.8 Clinical Trials

In Nepal, legal provisions exist requiring authorization for conducting Clinical Trials by the MRA [29, 30]. There are additional laws requiring the agreement by an ethics committee or institutional review board of the Clinical Trials to be performed [34, 35]. Clinical trials are required to be entered into a national registry, by law [34, 35]. Nepal Health Research Council, established as per the Nepal Health Research Council Act [34], is an organization for approving and monitoring health research activities.

## 5.9 Controlled Medicines

Nepal is a signatory to a number of international conventions, detailed in Table 12.

**Table 12: International Conventions to which Nepal is a signatory [36]**

| Convention | Signatory |
|---|---|
| Single Convention on Narcotic Drugs, 1961 | No |
| 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961 | Yes |
| Convention on Psychotropic Substances 1971 | Yes |
| United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988 | Yes |

Laws exist for the control of narcotic and psychotropic substances, and precursors [37]. The annual consumption of Morphine in 2009 was 6 Kg, that is 0.21395 mg/capita [36].

## 5.10 Pharmacovigilance

In Nepal, there are no legal provisions in the Medicines Act that provide for pharmacovigilance activities as part of the MRA mandate**.** Legal provisions do not exist requiring the Marketing Authorization holder to continuously monitor the safety of their products and report to the MRA. Laws regarding the monitoring of Adverse Drug Reactions (ADR) do not exist in Nepal. A national pharmacovigilance centre linked to the MRA exists.
The Pharmacovigilance centre has 1 full-time staff member.

The centre has not published an analysis report in the previous two years and it regularly does not publish an ADR bulletin. An official standardized form for reporting ADRs is used in Nepal. Information pertaining to ADRs is stored in a national ADR database.

The ADR database currently comprises 427 ADR reports, of which 106 have been submitted in the past 2 years. These reports are also sent to the WHO collaborating centre in Uppsala [38].

106 ADR reports from the database have been forwarded to the WHO collaborating centre in the past 2 years.

There is no national ADR or pharmacovigilance advisory committee able to provide technical assistance or causality assessment, risk assessment, risk management, case investigation and, where necessary, crisis management including crisis communication in Nepal. A clear communication strategy for routine communication and crises communication does not exist.

A number of steps are being considered in order to enhance Pharmacovigilance system. These include: DDA is functioning as National Pharmacovigilance Centre and six hospitals have joined as regional centres. More hospitals will be encouraged to join this programme. DDA will initiate awareness campaign on Pharmacovigilance and conduct training.

## Section 6 - Medicines Financing

In this section, information is provided on the medicines financing mechanism in Nepal, including the medicines coverage through public and private health insurance, use of user charges for medicines and the existence of public programmes providing free medicines. Policies and regulations affecting the pricing and availability of medicines (e.g. price control and taxes) are also discussed.

### 6.1 Medicines Coverage and Exemptions

In Nepal, concessions are made for certain groups to receive medicines free of charge (see Table 13). Furthermore, the government provides medicines free of charge for particular conditions (see Table 14).

**Table 13: Population groups provided with medicines free of charge**

| Patient group | Covered |
|---|---|
| Patients who cannot afford them | Yes |
| Children under 5 years of age | Yes |
| Pregnant women | Yes |
| Elderly persons and female community health volunteers | Yes |

As per the Interim Constitution 2007 of Nepal [21], every citizen shall have the right to basic health services free of cost from the State. The law is not inacted to regularise this provision. However, National Free Healthcare Services Programme (Operational Procedure) has laid down the procedure to provide the free services. There are 321 medicines (INN) in National List of Essential Medicines [39], out of which limited number of medicines are needed at the lower

level of health facilities. At present different dosage forms of 22 to 45 medicines are listed for free healthcare at various level of health facilities [40]. In addition, vaccines for expanded program on immunization, medicines for tuberculosis, leprosy, HIV/AIDS & STI Diseases, Malaria, Kala-azar are free-of-cost. Moreover, children under 5, pregnant women, elderly persons and patients who cannot afford have special provision in free healthcare service in addition to the services mentioned above.

**Table 14: Medications provided publicly, at no cost**

| Conditions | Covered |
|---|---|
| All diseases in the EML | No |
| Any non-communicable diseases | No |
| Malaria | Yes |
| Tuberculosis | Yes |
| Sexually transmitted diseases | Yes |
| HIV/AIDS | Yes |
| Expanded Programme on Immunization (EPI) vaccines for children | Yes |
| Other – Filariasis, Nutritional & Control of diarrhoeal diseases and ARI to children | Yes |

Drugs for above vertical health programs are provided free of cost from the program itself.

## 6.2 Patients Fees and Copayments

Co-payments or fee requirements for consultations are not levied at the point of delivery. Furthermore, there are no copayments or fee requirements imposed for medicines. Revenue from fees or from the sale of medicines is not used to pay

the salaries or supplement the income of public health personnel in the same facility. No copayment system is in practice. The registration fee previously charged to patient is now paid by government (at primary care level).

### 6.3 Pricing Regulation for the Private Sector[vi]

In Nepal, there are legal or regulatory provisions affecting pricing of medicines [29].

These provisions are aimed at the level of manufacturers/retailers. Consumer Protection Act and Drug Act mention to print the retail price on the label and retailers should not sell above the retail price. It is applicable to all medicines equally.

The government does not run an active national medicines price monitoring system for retail prices. Regulations exist mandating that retail medicine price information should be publicly accessible [25]. Consumer Protection Act mentions to display the retail (and wholesale) price at the retailer level. However in practice, the price is printed on the label.

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

WHO/HAI pricing survey was not conducted in Nepal

#### *Availability*

Public sector availability of the medicines for free distribution is assured by effective logistics management information system and procurement system. Availability in the private sector is better due to commercial viability, large number of stockists, distributors and retailers.

#### *Pricing*

The Median Price Ratio is used to indicate how prices of medicines in Nepal relate to those on the international market. That is, prices of medicines have

[vi] This section does not include information pertaining to the non-profit voluntary sector

been compared to international reference prices[vii] and expressed as a ratio of the national price to the international price. For example, a price ratio of 2 would mean that the price is twice that of the international reference price. Calculation of Median Price Ratio is at the initial phase in Nepal.

***Affordability***

Affordability of medicines is measured in terms of the number of days' of wages necessary to purchase a particular treatment for a specific condition. The wage considered is that paid to the lowest paid government worker in Nepal. Some research was conducted in this area, but information is not available.

## 6.5 Price Components and Affordability

Survey on medicine price components was not conducted in Nepal.

## 6.6 Duties and Taxes on Pharmaceuticals (Market)

Nepal imposes duties on imported active pharmaceutical ingredients (APIs) and duties on imported finished products are also imposed. Value-added tax or other taxes are not imposed on finished pharmaceutical products. Provisions for tax exceptions or waivers for pharmaceuticals and health products are in place [41]. There are no duties on vaccines and blood products.

[vii] The International reference price is the median of prices offered by international suppliers (both for profit and not profit) as report by MHS International Price Indicator Guide (http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=DMP&language=English). For more information on the methodology WHO/HAI pricing survey, you can download a free copy of the manual at http://apps.who.int/medicinedocs/documents/s14868e/s14868e.pdf.

[viii] Import tariff may apply to all imported medicines or there may be a system to exempt certain products and purchases. The import tax or duty may or may not apply to raw materials for local production. It may be different for different products. *[In*: *HAI/WHO Measuring medicine prices, availability, affordability and*

# Section 7 - Pharmaceutical procurement and distribution in the public sector

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

## 7.1 Public Sector Procurement

Public sector procurement in Nepal is both centralized and decentralized. As per "Central Bidding and Local Purchasing Guidelines 2009" [42] all essential medicines for free distribution will be decided at the centre and 70% of the total procurement is done by this process. To maintain the buffer stock of medicine or to purchase when there is shortage of stocks, 10% budget is allocated for regional health directorate and 20% budget to the district. This procedure has the benefit of economy of scale, at the same time mechanism to address any shortage of medicine immediately. For public sector procurement, Public Procurement Act [43] and Public Procurement Regulations [44] must be followed.

The public sector procurement is centralized under the responsibility of a procurement agency which is a part of the Ministry of Health and Population.

Public sector request for tender documents are publicly available and public sector tender awards are publicly available [45]. Procurement is not based on the prequalification of suppliers.

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*price components (2nd Edition) and at: http://www.haiweb.org/medicineprices/manual/documents.html]*

## 7.2 Public Sector Distribution

The government supply system department in Nepal has a Central Medical Store at National Level (also known as Logistics Management Division). There are 5 public warehouses in the secondary tier of the public sector distribution. There is no national guideline on Good Distribution Practices (GDP). A licensing authority that issues GDP licenses does not exist.

## 7.3 Private Sector Distribution

Legal provisions exist for licensing wholesalers and distributors in the private sector.  Wholesalers and distributors are not GDP certified.

## Section 8 - Selection and rational use of medicines

This section outlines the structures and policies governing the selection of essential medicines and promotion of rational drug in Nepal.

### 8.1 National Structures

A National Essential Medicines List (EML) exists [39].The EML was lastly updated in 2011 and is publicly available.
There are currently 321 medicines on the EML. Selection of medicines for the EML is not undertaken through a written process.  A mechanism aligning the EML with the Standard Treatment Guidelines (STGs) is in place.

National Standard Treatment Guidelines (STGs) for the most common illnesses are not produced/endorsed by the Ministry of Health and Population in Nepal. Specific STGs cover primary care at health post and sub-health post level. Standard Treatment Schedules for Health Post and Sub-health Post [46] was updated in 1999.

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

A written National Strategy for containing antimicrobial resistance does not exist.

## 8.2 Prescribing

Legal provisions exist to govern the licensing and prescribing practices of prescribers [47, 48]. Furthermore, legal provisions restricting dispensing by prescribers exist [29]. Prescribers in the private sector do not dispense medicines.

There are regulations requiring hospitals to organize/develop Drug and Therapeutics Committees (DTCs) [49].

The training curriculum for doctors and nurses is made up of a number of core components detailed in Table 15.

**Table 15: Core aspects of the medical training curriculum**

| Curriculum | Covered |
|---|---|
| The concept of EML | Yes |
| Use of STGS | Yes |
| Pharmacovigilance | Yes |
| Problem based pharmacotherapy | Yes |

Mandatory continuing education that includes pharmaceutical issues is not required for doctors/nurses/paramedical staff.

Prescribing by INN name is not obligatory in the public/private sector.

## 8.3 Dispensing

Legal provisions in Nepal exist to govern dispensing practices of pharmaceutical personnel [29]. The basic pharmacist training curriculum includes a spectrum of components as outlined in Table 16.

**Table 16: Core aspects of the pharmacist training curriculum**

| Curriculum | Covered |
|---|---|
| The concept of EML | Yes |
| Use of STGS | Yes |
| Drug information | Yes |
| Clinical pharmacology | Yes |
| Medicines supply management | Yes |

Mandatory continuing education that includes rational use of medicines is not required for pharmacists.

Substitution of generic equivalents at the point of dispensing is not allowed in public and/or private sector facilities. Sometimes antibiotics are sold over-the-counter without a prescription. Sometimes injectable medicines are sold over-the-counter without a prescription.

## Section 9 - Household data/access

In the past 5 years, household survey has not been undertaken to assess the access to medicines.

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