UNEDITED VERSION

STUDY OF
THE NEPALESE PHARMACEUTICAL INDUSTRY
IN THE CONTEXT OF
NEPAL'S NEWLY ACQUIRED
WTO MEMBERSHIP

Submitted to
South Asia Watch on Trade, Economics and Environment (SAWTEE)
Kathmandu, Nepal

Submitted by

Pulchowk, Lalitpur
Nepal

In Association with
Center for Gender and Management
Lal Durbar Marg, Kathmandu
Nepal

and

Road No. 1, Banjara Hills,
Hyderabad – 500 034
India

December 2005

List of Abbreviations

1	APPON	Association of Pharmaceutical Product of Nepal
2	DDA	Department of Drug Administration
3	DOI	Department of Industry
4	DOSCI	Department of Small and Cottage Industry
5	EMS	Environment Management System
6	FNCCI	Federation of Nepal Chamber of Commerce and Industry
7	GATT	General Agreement on Trade and Tariff
8	GMP	Good Manufacturing Practice
9	GPAN	Graduate Pharmacist Association of Nepal
10	HRD	Human Resource Development
11	LDC	Least Development Country
12	MNC	Multi-National Country
13	MOHP	Ministry of Health and Population
14	MOICS	Ministry of Industry, Commerce and Supplies
15	NCDA	Nepal Chemist and Drug Association
16	NMA	Nepal Medical Association
17	PAN	Pharmacist Association of Nepal
18	QC	Quality Control
19	QMS	Quality Management System
20	R & D	Research and Development
21	SAARC	South Asia Association of Regional Cooperation
22	SAFTA	South Asia Watch Free Trade Agreement
23	SAWTEE	South Asia Watch on Trade, Economics And Environment
24	SPS	Sanitary And Phyto- Sanitary
25	TBT	Technical Barriers to Trade
26	TPC	Trade Promotion Center
27	TRIPS	Trade Related Aspects of Intellectual Property Right
28	USFDA	United State Food and Drug Authority
29	WHO	World Health Organization
30	WTO	World Trade Organisation

TABLE OF CONTENTS

INDIVIDUALS INVOLVED

Team Leader

Ramesh Man Singh Maskey
Managing Director
Matrix Services Plc.
Lalitpur, Nepal

Consulting Team

Mahesh Gongal Director Centre for Gender & Management Kathmandu, Nepal	Productivity, Quality & Competitiveness Expert
Devashish Banerjee Managing Director Cygnus Hyderabad, India	Pharmaceutical Sector Expert
Ajay Bahadur Pradhanang Matrix Services Plc. Lalitpur, Nepal	Quality Consultant
Madhuri Newa Matrix Services Plc. Lalitpur, Nepal	Pharmacist
Pratistha Srivastav Research Executive Matrix Services Plc. Lalitpur, Npal	Research Analyst
Kalyan Adhikari Business Development Associate Matrix Services Plc. Lalitpur, Nepal	Research Associate
Shekhar Maskey Research Associate Matrix Services Plc. Lalitpur, Nepal	Research Associate

ACKNOWLEDGEMENT

We are grateful to the South Asia Watch on Trade, Economics and Environment (SAWTEE) for entrusting us to carry out this study. We are also grateful to all the members of the Working Team, who has made this study a successful one. The successful completion of the study would not have been possible without the help and support of various people from Ministry of Industry, Commerce, and Supplies (MOICS), Ministry of Health and Population (MOHP), Department of Industry (DOI), Department of Health Service (DOHS), Department of Drug Administration (DDA), Association of Pharmaceuticals Producers of Nepal (APPON), Nepal Chemist and Druggist Association (NCDA), Pharmacists Association of Nepal (PAN), and Graduate Pharmacist Association of Nepal (GPAN) individually and collectively.

We are thankful to Mr. Bhupendra Bahadur Thapa, Director, Department of Drug Administration; Mr. Umesh Lal Shrestha, Secretary General, Association of Pharmaceutical Producers of Nepal; Dr. Sudha Sharma, President, Nepal Medical Association and Mr. Mahendra Bahadur Amatya, Managing Director, Nepal Pharmaceuticals Laboratories Pvt. Ltd., for their valuable suggestions and expert advices, which has led us in the right direction in carrying out our activities. We are also thankful to Mr. Mukunda Ram Bhandary, Senior Consultant for his support during study period. Thanks are due to all the individuals and institutions providing information, opinions and suggestions to us for the study.

Ramesh Man Singh Maskey
Team Leader

EXECUTIVE SUMMARY, CONCLUSION AND RECOMMENDATION

1. Introduction

Accession of Nepal to WTO on April 23, 2004 has brought both opportunities and challenges to Nepalese pharmaceutical industries. World market of pharmaceutical products is now open to Nepalese industries and simultaneously Nepalese market is open to industries worldwide. In this context Nepalese pharmaceutical industries need to be able to explore the opportunities and make best use of the opportunities while identifying the external threats to be over commed. Therefore, it has become necessary for Nepalese pharmaceutical industries to formulate the strategies that could lead them to their growth and also harness their strengths for exploiting the opportunities before stepping into WTO/TRIPS regime in 2016. This necessitated undertaking a study giving recommendations to pharmaceutical industries in light of WTO and also giving recommendations to the government and associations relating to the industries that would enable the industries to fulfill above needs. This report is the outcome of the study.

2. Nepalese Pharmaceutical Industry

Nepalese pharmaceutical market is estimated at Rs 8649 million and is growing at a compounded annual growth rate of 10% percent. The market is highly import driven (about 70 %) with the highest per capita of brands. Imports from India make for highest share of total imports. Off late, the domestic manufacturers have made their presence felt in the market with sizable presence in the top five therapeutic segments namely anti-invectives, respiratory, vitamins/minerals, gastro intestinal and pain/analgesic segments. The domestic players import all the raw materials needed for production of formulations. Among the domestic producers as per the industrial classification, there are five players in the small scale, 29 in the medium scale and the rest five in the large scale. All of these are catering domestic demand and none is exporting its products at present

The major issues and challenges of the domestic pharmaceutical industry identified are high dependence on imports, low tariff barrier for imports, high proliferation of brands, unregistered drugs in border market, lack of reverse engineering skills, low research & development investment, high costs of production, poor healthcare

infrastructure, security concerns inhibiting the rural drug consumption, constraints to export, etc. The strengths, the industry possesses are suitable production facilities, good quality product, well qualified and experienced human resources, knowledge of market, and high level of private participation. Similarly the weaknesses it has are poor capacity utilization, poor financial return hampering investment for future development and growth, lack of highly skilled technical personnel, low level of institutionalization, poor supply-chain management, ineffective business linkages and others. The Nepalese pharmaceutical industries have good business outlook due to favorable government policies, existing and potential markets both domestic and export, new openings due to provisions of SAFTA and WTO/TRIPS, growth in health institutions and health awareness, and others. The major threats identified are emergence of competition; absence of institutions for support and facilitation for quality assurance and R & D, restriction to produce generic versions of patented products, poor implementation of policies and regulations, etc. The critical core success factors for pharmaceutical industries are noticed to be marketing, product quality; product portfolio; possession of quality certifications, demand fulfilling capability, economy of scale, and research and development.

3. World Trade Organization (WTO) and Provisions of TRIPS for Least Developed Countries

The major agreements of the WTO that affect the pharmaceutical industry are: General Agreement on Tariff and Trade 1994, Agreement on Trade Related Aspects of Intellectual Property Rights, Agreement on Technical Barriers to Trade and Agreement on Sanitary and Phytosanitary Measures. Among others, the TRIPS agreement has a major affect on the pharmaceutical industry. Looking at the preparedness and the public health, the exemption for adhering to the patent recognition and data protection was extended to January 1, 2016 for the members of WTO who are classified as Least Developed Countries by United Nations. Nepal which has signed WTO agreement on April 23, 2004, falls under LDC, and therefore has time till 1st January 2016 to enforce the product patents and data protection in the pharmaceutical.

4. Effect of WTO

The major impact of WTO on the Nepalese pharmaceutical industry which comprises mostly of small and medium scales will be loss of business for companies producing drugs which are in patent period by reverse engineering. The companies can't introduce new drugs into the market in the patent period any more unless they have a license from the innovator. This would mean higher price for the newly introduced patented drugs. On the other hand for the domestic pharmaceutical companies they have the options of catering only to the generics and contract manufacturing market. The agreements of WTO stipulate that the exporting countries should follow the current WTO Good Manufacturing Practices for the drug production, which would mean additional investments for most of the Nepali pharmaceutical companies which are mostly small and medium ones. However one saving feature is a provision by which the Government can introduce compulsory licensing for drugs in the event of emergency in national interest, effectively limiting the influence of Trade Related Aspects of Intellectual Property Rights (TRIPS) on the society.

5. Enhancing Competitiveness

Competitiveness of industries under could be enhanced through the enhancement of quality and productivity of the sector or its industries. Therefore, the steps to be taken by the Nepalese pharmaceutical industries to enable them to capitalize on the opportunities and face up to the challenges would be those measures, which would enhance quality and productivity of the industries in isolation or in combination. The steps identified enhancing competitiveness are: a) quality enhancement through plant facility certification (WHO-GMP Certification) Quality Management System (QMS) and Environment Management System (EMS), and stringent adoption of quality standards; b) enhancing productivity through attaining economy of scale, reduction in costs, improving effectiveness; and c) innovation through research & development, institutionalization, and collaboration.

7. Conclusion and Recommendations

Accession of Nepal to WTO has brought both opportunities and challenges to Nepalese pharmaceutical industries. World market of pharmaceutical products is now open to Nepalese industries and simultaneously Nepalese market is open to

industries worldwide. In this context Nepalese pharmaceutical industries need to be able to explore the opportunities and make best use of those. In addition, those industries also need to identify the external threats for them and make efforts to overcome the threats. Apart from these, Nepal being categorized as a Least Developed Country has to recognize the product patents from January, 1, 2016. With these opportunities and challenges the Nepalese pharmaceutical industry has to develop and implement strategies to sustain and grow with prevailing competition from the imported products along with preparing themselves for the year 2016, wherein the product patents will be recognized in every part of the world. The government and pharmaceutical association have also to take certain measures by which the industries could attain their objectives. Based on the study of present status; and analyses of opportunities and challenges for Nepalese pharmaceutical industries in the wake of WTO, recommendations are made for government, private sector industries, and associations related to pharmaceutical industry.

As a strategy, the industries should look to upgrade production facilities, attain economy of scale, reduce production costs, use common facilities, expand market, undertake research & development, develop human resources, develop alliances, develop work relationships, and initiate institutionalization process within the industries.

The government is recommended to introduce and implement acts, regulations and policies productively, establish supportive and facilitative institutions for pharmaceutical industries, build capability of regulatory bodies, utilize provisions of WTO productively, make trade alliance with other countries, develop and expand health facilities, and provide incentives to industries, and make efforts to extend the time frame by a decade.. Similarly, pharmaceutical association is recommended to strengthen its capability to serve the industries; launch HRD programmes; assist industries with information on WTO and others. It is also strongly recommended that a detailed study should be undertaken this theme.

1. INTRODUCTION

1.1 Background

Nepal has become a WTO member on April 23, 2004. Accession of Nepal to WTO has brought both opportunities and challenges to Nepalese pharmaceutical industries. World market of pharmaceutical products is now open to Nepalese industries and simultaneously Nepalese market is open to industries worldwide. In this context Nepalese pharmaceutical industries should be able to explore the opportunities and make best use of the opportunities. In addition, Nepalese industries should also identify the external threats for them and make efforts to overcome the threats. Therefore, it has become imperative for individual Nepalese pharmaceutical industries and Pharmaceutical Industry as a whole to formulate the strategies which could lead them to their growth and how they could harness their strengths for exploiting the opportunities before stepping into WTO/TRIPS regime in 2016. Since majority of pharmaceutical industries in Nepal are SMEs, there is a necessity for a facilitating role by the government for gearing-up Nepalese industries to utilize the opportunities under WTO regime. Therefore, it is also imperative to identify the roles to be played by the government to facilitate the Nepalese pharmaceutical sector to enter WTO regime. With a view to fulfill these needs this study has been carried out.

1.2 Objective

The objective of the study is to identify strategies to be adopted by Nepalese Pharmaceutical Industry to grow and harness their strengths for tapping the opportunities before stepping into WTO/TRIPS regime in the year 2016, and to identify government's role in facilitating Nepalese Pharmaceutical Industry to gear up for the WTO regime. This study also intends to provide recommendations to government agencies, pharmaceutical industries and association to attain above envisaged objectives.

1.3 Scope

The scope of the study is to cover the followings aspects:

i. Overview of the Nepalese Pharmaceuticals Industry:

   a) Industry Structure

b) Issues and Challenges

c) Competitiveness in the domestic and potential export markets

d) SWOT analysis of Nepalese Pharmaceutical Industry.

e) Issues facing the small and medium enterprises: manufacturing, R & D, marketing etc.

f) Critical success factors.

ii) Provisions of WTO/TRIPS, affecting the Pharmaceuticals sector in general.

iii) Provisions/Flexibilities of WTO/TRIPS for LDC and Analysis of its effect in Nepalese Pharmaceutical Industry.

iv) Steps to be taken to enhance the competitiveness of the Nepalese Pharmaceutical sector to enable them to capitalize on the opportunities and face the challenges.

v) Recommendation for Government agency, Private sector, Pharmaceutical associations and other related institutions compatible with WTO agreements and provisions such as Agreement on Technical Barriers to Trade (TBT) Agreement on Sanitary and Phytosanitary Measures (SPS) and General Agreement on Tariffs and Trade (GATT).

1.4 Methodology

The methodology adopted is as follows:

- Collection of data, information, documents, reports, published and other materials relating to pharmaceutical sector, WTO/TRIPS and others relating to the study; and undertaking of an initial desk research
- Based on the information gathered through desk research, identification of data and information necessary for the study along with identification of their sources, designing and development of questionnaires for necessary data and information collection and of their processing
- Pre-testing of the questionnaire designed and developed for data and information collection; and finalization of questionnaire with necessary modification after pre-tests A specimen of the Semi-structured questionnaire is presented as Appendix – 1.1

- Collection as well as collation of primary data and information through developed questionnaire; observations at industry sites; and in-depth meetings, interactions and consultations with representatives from governmental institutions, regulatory bodies and agencies like DDA, MOICS, DOI, TPC; from associations like FNCCI, APPON and from other key informants like importers, distributors, stockiest of pharmaceutical products and other stakeholders relating to the study. A list of the pharmaceutical industries contacted and individuals interviewed/consulted is presented in Appendix – 1.2. and Appendix – 1.3 respectively
- Processing and analysis of data and information, and drawing of inferences
- Preparation of a draft report covering all the aspects stated under the TOR of the study; and submission to SAWTEE
- Preparation and submission of the final report incorporating all the relevant comments and suggestions, to SAWTEE. The report presents an overview of Nepalese pharmaceuticals market at first. It presents WTO provisions affecting pharmaceutical industry; provisions for LDCs; effect of provisions on Nepalese pharmaceuticals industry; and steps to enhance competitiveness. The report presents recommendations to the government, pharmaceutical industry and associations to enable the Nepalese pharmaceutical industry to exploit the potential opportunities and challenge and to overcome the threats that could arise in the future.

1.5 Limitations:

The limitations are:

i. The recommendations given are based on perspective of the present status of the Nepalese pharmaceutical industry and the opportunities vis-à-vis the changing regulatory environment in the context of WTO. As the period of 10 years is a considerable time frame for any industry in changing its dynamics, the recommendations are of macro perspective as well as of micro or short term in nature.

ii. Most of the Nepalese Pharmaceutical Industries were not able to articulate the threats the industry is currently facing and the impact of WTO regime

on them. Therefore, the section of the study related to WTO, the perspectives from the Nepalese industry are considerably less and taken analogy from the other markets, where WTO agreements were recognized.

2. OVERVIEW OF NEPALESE PHARMACEUTICAL INDUSTRY

2.1 Industry Structure

2.1.1 Domestic Pharmaceutical Industries

As per DDA there are 39 pharmaceutical industries in operation at present in Nepal. According to the Industrial Enterprise Act 1997 and subsequent amendments, industries with the capital investment upto Rs 30 million is considered as small scale industries and those between Rs 30 million to 100 million is considered as medium scale industries. The industries with capital investments more than Rs 100 million are categorized as large scale industries. Of the above 39 industries, 5 units are of small scale, 29 units in medium scale, and the rest 5 in large scale.

Majorities of these units are located in Kathmandu Valley and Narayani Zone, while the rest are scattered in places like Janakpur, Biratnagar, Bhairahawa, Dharan. Except the Royal Drugs Limited, all the pharmaceutical units are in private sector and registered as private limited company. The list of pharmaceutical units along with their location is presented in Table No, 2.1.

Table No. 2.1 : Pharmaceutical Companies Registered with DDA

S.No	Name Of Company	Location
1	Alive Pharmaceuticals Pvt.	Biratnagar
2	Alliance Pharmaceuticals Pvt. Ltd	Simra, Birgunj
3	Amie Pharmaceuticals Pvt Ltd	Janakpur
4	Apex Pharmaceuticals Pvt.Ltd	Parwanipur, Birgunj
5	Arya Pharmalab Pvt. Ltd.	Rampur, Kokani, Parwanipur, Birgunj
6	Asian Pharmaceuticals Pvt. Ltd.	PPadsari, VDC-9 Rupendehi, Bhairahawa
7	Birat Pharma Lab Pvt. Ltd.	Biratnagar, Morang
8	Chemi Drug Industries Pvt Ltd.	Bijeshwori, Kathmandu
9	Concept Pharmaceuticals (N) Pvt. Ltd	Birgung
10	CTL Pharmaceutical Pvt. Ltd	Sallaghari,Bhaktapur
11	Curex Pharmaceuticals Pvt. Ltd.	Janagal, Benepa, Kavre
12	Danium Laboratories (P) Ltd.	Parwanipur, Birgunj
13	Deurali-Janata Pharmaceuticals Pvt. Ltd.	Dhapasi,Kathmandu

14	Dingla Pharmaceuticals (P) Ltd.	Biratnagar
15	Everest Pharmaceuticals Pvt. Ltd	Kuleswor Aavas chhetra Kuleswore, Kathmandu
16	Florid Laboratories Pvt. Ltd.	Dhapakhel VDC, WNO 8, Lalitpur
17	G.D. Pharmaceuticals Pvt. Ltd.	Birgunj, Parsa
18	Hukum Pharmaceutical Pvt. Ltd.	Thimi, Bhaktapur
19	Lomus Pharmaceuticals Pvt. Ltd.	Gongapu, Ringroad, Kathmandu
20	Mark Laboratory	Thankot
21	Manoj Pharmaceuticals Works Pvt. Ltd.	Industrial Estate ,Dharan
22	Milan Pharmaceuticals Pvt Ltd	Biratnagar
23	National Health Care Pvt. Ltd.	Nitanpur, Chhatabibra, Bara
24	National Pharmachem	Janakpur
25	Nepal Pharmaceuticals Lab. Pvt. Ltd	Jeetpur, Birgunj, Parsa
26	Ominica Laboratoriies Pvt Ltd.	Chitapole VDC-1 Banshghari, Bhaktapur
27	Pharmaceutical Company of Nepal Pvt Ltd	Motisar, Bara
28	Pharmaco Industries Pvt.Ltd.	Chhetrapati, Dhalko, Kathmandu
29	Quest Pharmaceuticals Pvt. Ltd.	Chhatapipra, Bara
30	Royal Drugs Limited	Babarmahal, Kathmandu
31	Shiv pharmaceuticals Laboratories Pvt. Ltd	Dharan
32	Siddhartha Pharmaceuticals Pvt. Ltd.	Madhyawaliya, Rupundehi, Bhairahawa
33	Simca Laboratories Pvt. Ltd.	Balkumari, Thimi, Bhaktapur
34	S.R.Drug Laboratories Pvt. Ltd	Satungal VDC, Kathmandu
35	Summy Pharmaceuticals Ltd	Nawalparasi
36	Time Pharmaceuticals Pvt. Ltd.	Mukundapur WNO 5
37	Unique Pharmaceuticals (P) Ltd.	Chhatapipra, Bara, Birgung.
38	Vijayadeep Pharmaceuticals P. Ltd.	Saibu VDC, W.NO 4, Lalitpur
39	Vijaydeep Laboratory	Saibu VDC, W.NO 4, Lalitpur
Source: Drug Bulletin Published by DDA.		

All pharmaceutical industries produce pharmaceutical products in tablet and capsule forms while a limited number of units produce products in liquid, ointment, dry syrup, powder forms. Of those only two units produces IV Fluid and

a another one the injectables. Majority of the industries are producing same group of products, but some have started producing cardiovascular, psychotropic and anti-diabetic products too. Only two industries are producing I V Fluid i.e. Dextrose. Of all 39 industries only 5 have acquired WHO Good Manufacturing Practice (GMP) certification, which are namely Nepal Pharmaceutical Lab, National Health Care, Quest Pharmaceuticals, Deurali Janata and Omnica Pharmaceuticals. A few are in the process of getting WHO-GMP certificates. Only two industries, namely Deurali Janata Pharmaceuticals , Hukum Pharmaceuticals and National Healthcare have acquired ISO 9001:2000 and ISO 14000 Certifications so far. Most of the pharmaceutical industries are owned and/or managed by the people, who were either traders of pharmaceutical products or individuals marketing pharmaceutical products of Indian or multinational companies in Nepal.

2.1.2 Market

a. Consumption and Market Share

As per the study by DDA of 2001, domestic consumption of allopathic medicine in the fiscal year 2000/01 amounted to Rs. 5,907 millions and the study has also forecasted annual compounding growth rate of 18.8 % up to the year of 2005/06. But the consumption did not rise to that level due to political disturbances affecting the distribution of medicine in the hilly and mountainous region of central and eastern part, and western part of the country. The poor consumption of allopathic medicine was also due to less supply of such products by the government to its health institutions of affected areas for fear of looting by insurgents. Effort was made to estimate the growth rate by interviewing key informants relating to it, which has helped in ascertaining the compounded annual growth rate as 10%. Based on this growth rate, the consumption of allopathic medicine for the year 2004/05 is estimated at Rs. 8,570 millions. The share of domestic producers is noticed to rise gradually. As per the Org-IMS MAT March 2004, Nepalese producers hold a market share of 29%, Indian companies 54% and multi national companies 17% in 2004, which were 21%, 22% and 57% respectively in the year 2000. As per the authority of the DDA the market share of Nepalese producers is slightly higher than above and is

estimated at about 35%. The population using the modern medicine is about 25% of total population due to factors like socio-cultural beliefs, wide spread ignorance, illiteracy and inadequate health services.

The top five therapeutic segments in the market are anti-infective, respiratory, vitamins/minerals, gastro intestinal and pain/analgesic segments together accounting for about 68 per cent of the retail pharmacy sales as per ORG-IMS MAT March 2004.

b. Major Companies in Market

The Nepalese pharmaceutical market has one of the highest brands Per capita and is highly import driven. The market is highly dependent on import from domestic and multinational companies of India, Bangladesh, and others. The number of pharmaceutical companies by country of origin registered at DDA is presented in Appendix – 2.1. The top 10 companies hold 33% of the total retail pharmacy market by sales value and the next top 30 companies hold 62% of the market. The top 10 pharmaceutical companies in retail market are given in Table No. 2.2.

Table No. 2.2: Top 10 Pharmaceutical Companies in Retail Market

S.No	Company	Country of Origin
1	Lomus	Nepal
2	Nepal Pharmaceuticals.	Nepal
3	Deurali-Janata	Nepal
4	Aristo	India
5	Dabur	India
6	National H.C	Nepal
7	Knoll	MNC
8	Ranbaxy	India
9	Nicholas	India
10	Alkem	India

Source: Org-IMS MAT March 2004

c. Major Products In Market

The top 10 pharmaceutical products based on sales value in the market are largely dominated by those of the Indian companies. Those have earned

this position by virtue of being in the market the longest. In addition, better marketing and promotion, and an impression of superior quality have kept them on the top 10 list. Off late the Nepalese pharmaceutical companies are able to make their entry into the top 20 products with brands like Nemox, De Cold, Brucet, Reymoxis, etc. produced by National Healthcare Private Limited, Lomus Pharmaceuticals, Nepal Pharmaceutical Laboratories Ltd, Deurali Janata.. The top 10 products along with their producers are given in Table No. 2.3.

Table No. 2.3: Top 10 Products in the Market

S. No	Brands	Company
1	Althrocin	Alembic
2	Keflor	Ranbaxy
3	Digene	Knoll Pharma
4	Rabipur	Aventis
5	Megapen	Aristo Pharma
6	Sporidex	Ranbaxy
7	Distaclor	Eli Lilly
8	Chyawanprash Avaleh	Dabur
9	Clavam	Alkem
10	Strepsils	Nicholas Piramal

Source: Org-IMS MAT March 2004

d. Sales and Distribution System

All pharmaceutical industries are marketing their products solely within the country. Their pharmaceutical products reach the end users through a four–tier distribution system consisting of distributors, stockiest, sub stockiest and retailers. According to the recent statistics of the DDA, there are 2,350 medical wholesalers and 18,255 pharmacies that are operating in the country.

e. Exports/Imports

None of the Nepalese pharmaceutical companies is exporting its products at present, though two companies had exported to India earlier. Those two could not continue their export due to long time taking cumbersome

beurocratic hurdles effecting the shelf-life of the products not sufficient as per regulatory requirement . On the other hand the market is largely import dependent. Nepal has imported pharmaceutical products worth of Rs 6,034 millions in the fiscal year 2003/04, which is 69.7% of the total domestic market (i.e., Rs. 8,649 millions). As per Org-IMS MAT March 2004, the top brands are: Althrocin (Alembic), Keflor (Ranbaxy), Digene(Knoll Pharma), Rabipur (Aventis), Megapen (Aristo Pharmaceuticals), Sporidex (Ranbaxy), Distaclor (Eli Lilly), Clavam (Alkem), all of which are from India. The latest available break up of top pharmaceutical product groups imported by Nepal in FY 2001 is as given in Appendix - 2.2.

2.1.3 Main and Auxiliary Raw Materials

Nepalese pharmaceutical industries are dependent of import for bulk drugs and active pharmaceutical ingredients. The major source for importing bulk drug and active pharmaceutical ingredients for medicines is India. The others are China, Belgium, South Korea, Australia, Denmark, Holland and Switzerland. Other requirements of the domestic producers like binders, diluents, disintegrants, glidants for tablets, capsule shells for capsules, suspending agent for suspensions, sweetening agents, colors, preservatives, antioxidants and other auxiliary materials are also met from India.

2.1.4 Capacity Utilization

Capacity utilization of pharmaceutical industries is noticed to vary from 25% to 80% depending upon the scale and product range. Industries of large scale with relatively larger range and form of products have 60% and above. The poor capacity utilization in pharmaceutical sector is said to be due to less product range and form, and also installation of plant and machineries of higher capacity than required due to lack of knowledge and information at the time of establishment.

2.1.5 Technology

The technologies used to manufacture pharmaceutical products in Nepalese industries differ from semi-automatic to automatic depending upon the form of pharmaceutical product. – Tablets, capsules, liquid, ointment, dry syrup, powder, injectables etc. The machineries used to manufacture pharmaceutical product are mostly from India. But instruments and equipment for quality control and quality

assurance are mostly from third countries like Singapore, Japan, Germany, etc. All the industries have incorporated quality control in its production process, but only a few have system for quality assurance. With a view to enhance technology and quality of the sector, two industries have come forward and developed linkages with academia. Only one industry has technical collaboration with Bangladesh Company.

2.1.6 Human Resources

Except highly skilled technical manpower there are enough human resources available for Nepalese pharmaceutical industries to carry out pharmaceutical formulation, production and marketing of formulated finished products, as Nepal has sufficient number of qualified pharmacist, chemist and skilled technical manpower required for above. Therefore, all domestic pharmaceutical industries are having Nepalese production and marketing manpower. But in case of highly skilled technical manpower capable of undertaking R & D, quality assurance, and complex formulations; the requirement is met from India and abroad.

2.1.7 Research and Development

Research & development in Nepalese pharmaceutical industries is limited to pharmaceutical formulation and testing only. No industry has enough capability for carrying out R & D for reverse engineering of new molecules. Even the Royal Drugs Research – a governmental laboratory established three decade ago to carry out researches in drug is limiting its activities only in drug testing. Three laboratories under the private sector are capable of drug testing activity in a limited scale.

2.2. Issues and Challenges

There exists a number of issues and challenges that Nepalese pharmaceutical sector is facing. The major issues and challenges are as follows:

2.2.1 High Dependence on Imports

The Nepalese pharmaceutical market is highly dependant on the imports, because about 69.7 per cent of the market (Rs 8649 million) is catered through imports. Such high dependence on the imports is very critical for any pharmaceutical market. Although the issue of higher price is not a

concern in the market due to a large number of companies in the generic market at present, but it would definitely be a major issue in a patent recognized import driven market. Therefore, Nepal needs to move towards a self-dependent vibrant domestic pharmaceutical market. Likewise, all ingredients like bulk drugs and active pharmaceutical ingredients for Nepalese pharmaceutical sector are required to be imported from outside making the sector totally dependent on imports.

2.2.2 Low Tariff Barriers for Import of Drugs

Only 5% customs duty is levied on the imported drugs, whereas domestic industry has to pay upto 17 per cent in the form of duty including Value Added Tax on imports of packaging and others auxiliary inputs. These increase the cost of production affecting the competitiveness of Nepalese industries. (Note: Recently government removed VAT through Financial Ordinance on 14 Jan, 2006)

2.2.3 Constraint to Export

The neighboring markets for the Nepalese pharmaceutical industry are China, India, Pakistan and Bangladesh, but most of these markets are more or less self-sufficient with the well developed domestic pharmaceutical industries. Export potential in other countries is limited due to less access of market and regulatory information, higher transport costs and high registration costs in export markets. For example, with the enactment of a regulation enforced since April 2003, Nepali drug companies have to pay US $ 1,500 as a registration fee at Central Drug Lab of India prior to exporting drugs to Indian market, while Indian companies have to pay just Rs 50,000 to DDA, Nepal for exporting their medicines to Nepal. Along with the high registration charge, the amended Act has also imposed different new fees including factory inspection charge amounting to US $ 5,000 and quality examination fee of US $ 1,000 to each new brand of the foreign drug exported to India. While the Indian companies are taking the advantage of the low drug registration fees in Nepal, Nepalese companies have to pay exorbitant fees in India reducing their competitiveness in Indian market. The Indian process for importing medicines from Nepal is

long and cumbersome causing difficulty in export. As Nepal is a land locked country, export from Nepal needs to overcome many hurdles in course of transit and transfer of products. Currently, the only option Nepalese industries have is routing through either India (Kolkatta port) or Bangladesh (Chittagong Port) to export medicines is by air transport. Moreover, infrastructures in those ports are relatively very poor and bureaucratic processes are cumbersome affecting the shelf-life of medicines as well as cost of exports from Nepal.

2.2.4 Proliferation of Brands

Nepalese pharmaceutical market has high proliferation of brands and in fact it is one of the markets having high per capita of brands. The brands available in Nepal by therapeutic groups are presented in Appendix – 2.3. It is not due to the foreign companies alone, as domestic companies too have good number of brands in the market. With the increasing number of brands, the marketing and sales budget of the companies are increased drastically affecting their competitiveness. This is because the companies have to establish high recall of their brands in the market through planned marketing and heavy sales promotion. The only differentiation in a generic market where in the technological superiority lasts for a short time, is through heavy marketing and sales promotions with good distribution system. Even it would be difficult for the prescribing doctors to choose from the available brands in the market. In such a situation, there are higher chances of low customized medicine prescriptions, as the doctor can concentrate on the few brands at any given time in order to identify their responses.

2.2.5 Unregistered Drugs in Market

There are some substandard drugs available in the Nepalese market. Substandard drugs which are either diluted or don't meet the standards prescribed in the country's pharmacopoeia. The US Food and Drug Administration estimates that about 10 per cent of all drugs around the world are counterfeit and 60 per cent of them are found in developing countries. The World Health Organization estimates that 35 per cent of the

fake drugs produced in the world come from India, where about 20 per cent of all drugs sold are either fake or substandard. Sale of unregistered drugs is prevalent in Tarie regions due to open border with India. The monitoring and regulation systems aren't vigilant enough to meet this danger and are compounded by lax enforcement of prescription rules. Antibiotics are readily available across the counter in Nepal.

2.2.6 Low Research and Development

Nepalese pharmaceutical industry has a market of around Rs 2500 million. Since there are 39 industries in total, each industry has market of an average of Rs. 64 million. Of the total, most are of small and medium scales and only a few are of large scale enterprises. With such low average revenue and majorities of being of small and medium scale, most of the industries are not able to spend on research & development activities, not even into the reverse engineering of the molecule production. A low investment in R&D due to lack of incentives has hindered the industry from becoming self sufficient, be it in bulk drugs or formulations. Industries have to pay 20 per cent custom duty in import of instruments to be used in R&D. Pharmaceutical sector spending significant amount in R & D is noticed to be more dynamic and vibrant, which could be seen in the case of Bangladesh.

2.2.7 Poor Healthcare Infrastructure

Even compared with the ones of neighboring countries, healthcare infrastructure of Nepal is not a developed one and only people living in urban areas are able to use the available infrastructure. About 85 per cent of the rural population lacks even basic healthcare facilities. There is acute shortage of medical doctors. The total number of allopathic doctors is about 4000 and majority of them are staying in the capital and other major cities. The public and doctors ratio is approximately 6000:1. Health workers in rural health care, who serve most of the population, are isolated from specialist support and up to date information.

Nepal's average life expectancy varies greatly from 74 years in Kathmandu to 37 years in rural areas, and maternal mortality is among the highest in

the region. Infectious diseases, maternal and prenatal disorders, and nutritional deficiencies account for more than 2/3rds of the diseases in Nepal. One out of 11 children dies before they reach age of five. Most of these children die within their first year. Although children under the age of 5 represent only 16 per cent of the population, they contribute approximately half of the total burden of disease in the country. The poorly-resourced clinics are the only means of hope for healthcare in large areas of rural Nepal. The poor healthcare infrastructure is affecting in making people aware of modern medicine and slowing the growth of consumption of pharmaceutical products in the country.

2.2.8 Security Concerns Impeding Healthcare

Apart from the difficult terrains, insurgency and political instability are inhibiting the pharmaceutical industry in proper distribution of the drugs in several parts of the country. The most affected are the western, mid-western and far-west development regions. The mountainous and hilly regions of central and eastern development region are also affected except the Kathmandu Valley and other urban areas. Frequent bandhs (general strikes/closures) and blockades for days are preventing the smooth distribution of drugs. Many health institutions are unable to operate to its capacity due to security concerns.

2.3 Competitiveness in Domestic and Potential Export Markets

As most of the domestic industries have presence in the therapeutic segments like anti-infective, anti-inflammatory /analgesics, nutrient deficiency, respiratory, etc, they could explore business opportunities for such products in the global market. The potential global markets that Nepalese pharmaceutical industries can consider are presented in Appendix - 2.4. Although Nepalese pharmaceutical products are of good quality, those are relatively less competitive due to endogenous and exogenous factors as given below.

The major factors are:

a. Higher cost of production due to:

- High Tariff in imports of packaging and auxiliary inputs

- Total dependency in imports for bulk drugs and active pharmaceutical ingredients
- High cost of capital
- Dependency on foreign experts for manufacturing R & D, complicated formulation, and quality assurance
- Poor capacity utilization
- Higher export cost due to need for airlifting, bureaucratic processes, etc.
- Existence of ineffective and inefficient systems and processes of production as well as other management functional areas

b. Limited number of industries with WHO-GMP Certifications; and ISO Certifications necessary for quality assurance, and quality management systems.

2.4 SWOT Analysis of Nepalese Pharmaceutical Industry

2.4.1 Strengths

a. Production Facilities

Production facilities of most of the Nepalese pharmaceutical industries are upgraded and updated as per the market and GMP requirements. With a view to be able to address the market needs manufacturing research and development & QC activities are regularly carried out.

b. Product Quality

Quality of Nepalese pharmaceutical products is good and therefore, those have received well recognition from the medical doctors and medical practioners. As a result of this Nepalese industries have acquired 30% market share within a short span of time.

c. Human Resources

The human resources involved in production, quality control, manufacturing, R & D, and marketing are well qualified and experienced in their respective areas. Human resources involved in this sector are taken as an asset and therefore, majorities of industries are putting their emphasis on human resources development.

d. Knowledge of Market Including Interior and Micro-Interior

Pharmaceutical industries have acquired a good knowledge about domestic market including interior and micro-interior enabling it to enhance its agility. This has enhanced the industry to perform marketing functions: formulate and implement strategies, distribution, promotion, customer relations, etc.

e. High Private Sector Participation

All the industries except one are under the private sector and therefore, are relatively quick in decision making and flexible as per the market need

2.4.2 Weaknesses

a. Poor Capacity Utilization/Economies of Scale

The capacity utilization of 39 Nepalese pharmaceutical industries varies from 25 to 80%. Of these large scale industries (five in number) and a few having wide range and forms of products have it over 60%. The majorities have fairly low capacity utilization. The basic reasons behind it are identified as less product range and form of products compared to industries having higher capacity utilization and also installation of plant and machineries of higher capacity than required due to lack of knowledge and information on industry at the time of establishment.

b. Inability to Generate Enough Income to Invest in:

- R & D

- Quality Assurance System
- Human Resources Development for Highly Skilled Technical Personnel
- Productivity and competitiveness enhancement measures

c. Limited R & D Activities

Only a few industries are carrying out manufacturing R & D, that too with low level of spending. This is forcing a large number of industries to outsource formulation for new products, which can cost even the credibility/corporate image of the industries, if it fails.

d. Lack of Highly Skilled Technical Personnel

Industries lack highly skilled and experienced pharmaceutical personnel, who are capable of carrying out complex formulations and reverse engineering of new molecules

e. Limited Quality Assurance Systems

Only 5 companies have acquired WHO-GMP certification and three have ISO 9001:2000; and ISO 14000 certifications. Numbers of industries which don't have acquired certification also have quality assurance but not all industries. Acquiring of above certificates and up-gradation of production facilities by only a few industries is affecting the whole sector.

f. Poor Institutionalization in Industries

Although establishment of pharmaceutical industries in the country begun decades ago, institutionalization of those industries with vision, mission, objectives, management systems, procedures, and others is still in the initial stage. Therefore, most of those industries are still being run with entrepreneurial drive and not managerial drives. It is because majorities of the pharmaceutical industries are owned and/or managed by the people, who were either traders of pharmaceutical products or an individuals who were marketing pharmaceutical products of Indian or multinational companies in Nepal, lack managerial knowledge and experience necessary for

managing and operating industrial enterprises. Possession of entrepreneurial/trading knowledge and skills and not the managerial ones is limiting the institutionalization of pharmaceutical industries for their long term sustainability and growth.

g. Adoption of Unethical Marketing Practices

There exists a practice of adopting unethical marketing practices by industries to retain or increase market and market share. Cut throat competitions among industries are often noticed increasing bargaining power of buyers and middlemen. Push marketing strategy is also noticed to be adopted which is common for consumer goods.

h. Sticking to Me-too (Similar)Products

Majority of industries are engaged in producing "me-too" (Similar) products and are noticed to avoid producing other new necessary products for fear of losses. This poor risk taking capability is affecting a large number of Nepalese pharmaceutical industries.

i. Abuse of Co-Operation and Common Understanding among Pharmaceutical Industries

Absence of common understanding and mutual co-operation amongst industries is affecting in having common goal of sectoral development and promotion. Malpractices like recruiting trained manpower from competitor's industries are very common.

j. Poor Linkages with Academia

Only recently a pharmaceutical industry has developed and maintained relationships with academia for development of the sector through research and development, human resources development and other developmental works and another one has developed relationship with academia for research. Very weak or non existence of tri-partite work relationships among pharmaceutical industry, academia and government is hindering in undertaking of research and development in pharmacy at the

academic institutions with the governmental support and then commercialization of successful developments by the pharmaceutical industries.

k. Poor Business Relationship with Government

Only a few industries have good and well maintained business relationships with government health institutions, and are short listed to participate in government procurements of medicine. A bulk of the government procurement is done from drug producing companies, which are from India and abroad.

l. Weak Supply Chain

Although all the basic and auxiliary raw materials need to be imported regularly from outside the country, the majority of pharmaceutical industries has weak supply chain management affecting availability of the products in market and reduces in their productivity and return. This holds true even in distributing products in hilly and mountainous regions. The industries are still unable to reach many places where there exists potential market for their products.

m. K**nowledge on WTO/TRIPS**

Majorities of industries are unaware of provisions of WTO/TRIPS and their consequences to their business.

2.4.3 Opportunities

a. Favorable Government Policy

Government has categorized pharmaceutical sector as one of the priority sectors. The government is providing monetary and fiscal facilities and incentives to the sector for its development. It is providing incentives to the pharmaceutical industry like levying only one per cent customs duty for input materials, machineries, etc. No Value Added Tax is levied for the industry.

b. Existence of Domestic Market and Export Potential

There is enough domestic market for Nepalese pharmaceutical industries as those are catering only about 30% of the domestic demand. Similarly, there exists export potential for Nepalese products in non-regulatory markets and Non-WTO member countries. Nepal lies between two big economies, India and China, which are having large pharmaceutical markets with sizes of US $ 9.5 billion and US $ 6.5 billion respectively. With the increase in quality of products, domestic industries could start looking towards the export markets and also, become a contract manufacturer.

c. New Openings due to Provisions of WTO/TRIPS

As per the provisions of WTO/TRIPS, Least Developed Countries (LDCs) are obliged to provide patent only from January 2016. As per this provision Nepal needn't adhere to recognition of product patents and therefore, has the choice of exporting the drugs which are in patent period to other LDC and Non-WTO member countries. The transition period would be an opportunity for the domestic companies to transform into vibrant pharmaceutical companies as the opportunities in the domestic generic market itself are enormous (i.e., domestic companies account for only 30% of the total market). The domestic companies can introduce in the market the new molecules that are developed by the research based pharmaceutical companies and even can export to the LDC countries. Thus the companies have the option of doing the business with the least risk of investments till 2016. There are also facilities for parallel import and compulsory license, and Bolar's provision, which Nepal can exploit.

d. New Openings due to SAFTA

SAFTA has open new venues for Nepalese pharmaceuticals industries to take benefit from the regional markets e.g. Bhutan,

Maldives, which depend on import of medicine and others from SAARC members countries.

e. Restriction on Imports

The government has imposed restriction on importing pharmaceutical products produced by industries without WHO-GMP Certification limiting competition by such industries in domestic market.

f. Rise in Awareness about Healthcare

Nepalese have become more aware of healthcare needs and modern medicine developing good market potential to industries. Rise in literacy level among Nepalese has also increased demand by many folds.

g. Development and Growth in Health Institutions

Gradual development and growth in public as well as private health institutions in the country are generating good business outlook for pharmaceutical industries.

h. Emergence of Facilitating and Supporting Institutions

Emergence of institutions to assist and support industries to enhance their competitiveness supporting through provision of information etc. like SAWTEE

2.4 Threats

a. Emergence of Competition

WTO regime opens up the climate for entry of foreign companies including MNCs into the domestic pharmaceutical market. The domestic companies have to compete with well established companies. Companies from LDCs with advanced technology like Bangladesh could also easily enter Nepalese pharmaceutical market.

b. Restriction to Produce Generic Versions of Patented Products

Restriction to produce generic versions of patented products is to begin from January 2016 due to TRIPS agreement

c. Unethical Marketing Practices by Foreign Competitors

Adoption of unethical marketing practices by foreign competitors like provision of incentives e.g. giving equivalent quantities of products free to wholesalers or distributors and others. Incentives of that nature drive wholesalers or distributors to promote the sales of low quality drug manufactured by those foreign competitors. This results in substitution of good quality products by inferior products with higher margins by them

d. Short Product Life

Fast development of new molecules shortens the life of existing generic products. In such a situation MNCs will play a dominant role in new molecules, because of their investment and risk taking capability.

e. Lack of Support and Facilitating Institutions for R &D and Quality Assurance

As majorities of industries are small and medium scale industries, such industries are incapable to undertake research and development activities on their own. It is difficult even for the large scale industries to possess state of art R& D facilities and testing laboratories of its own as such facilities need high investment in terms of capital and human resources. There exists no such institution/ laboratory to carry R & D in pharmaceutical and testing laboratory except Royal Drugs Research laboratory, which has also limitations of its own to serve pharmaceutical industries . It has been functionary as testing laboratory only due to limited resources.

f. Weak Implementation of Government Policy

There are number of governmental policies, acts and regulations for development, promotion and regulation of pharmaceutical sector in the country. The pertinent ones with regards to pharmaceutical industries are Patent, Design and Trade Mark Act BS 2022 and its recent amendments; Drug Act 1978 and its regulations; National Health Policy 1991; and National Drug Policy 1995. Weak implementation of above policies, acts, regulations and others by the government is affecting the genuine industries to take full benefits from those.

g. I**nadequate/Poor Support of Government**

Government procurement policy is giving priority to price with no special concessions for domestic companies. To make the domestic industry more competitive Government has not introduced any compulsory measures to the Department of Health Services necessitating to purchase pharmaceuticals from domestic industries for distribution/supply to governmental health institutions like hospitals, primary healthcare centers, etc. It is procuring medicines through the open market at competitive prices, wherein the participation of the foreign companies is high. The major areas where the government support is lacking are in technology transfer assistance, financial assistance in terms of soft loans and subsidies, setting up a world class research laboratory, provision of necessary logistics for exports, provision of infrastructure and facilities for industrial expansion, establishment of institutions for development of highly skilled human resources, enhancement of productivity, quality, competitiveness and information centre.

h. Limited Capability of Institutions Supporting and Facilitating Industries

The institutions set-up for supporting and facilitating industries like APPON, Nepal Chemist and Druggist Association, etc. do have their limitations thus hindering those to serve to their full capacity. Such limitations are financial from donors, human resources and others. These associations are not able to assist Nepalese pharmaceutical industries with productive programmes and activities to support the development of Nepalese Pharmaceutical Industries.

i. Absence of Public and Private Partnership Arrangements

Technology, lifeblood of pharmaceutical industry, is very crucial for its overall development and therefore, demands partnership between public and private sector which is missing in Nepal. Royal Drug Research Laboratory, established in the public sector more than three decade ago is

functioning as a testing laboratory not as an eminent drug research and development laboratory and technology assisting centre for the industry. Such institutions could have been further developed with public private partnership arrangements, which could be a land mark for other private companies to follow.

j. Separate Industrial Areas for Pharmaceutical Industries

As majority of pharmaceutical industries belong to small and medium scale, they are not in position to invest heavily in infrastructure necessary for pharmaceutical industries. In such situation having a common infrastructure and facilities such as common efficient treatment plant, common testing facilities is beneficial to the sector. Nepal does not have a specified location dedicated for pharmaceutical industries so far.

2.5 Primary Survey

Out of 39 pharmaceutical industries in operation, the questionnaire was distributed to 30 industries. Only 15 industries returned the questionnaire that was administered during the primary research is given in the Annexure I. 62.5 percent of respondents were the medium scale enterprises while rest the 37.5 percent of them was of large scale enterprises. None of the small scale enterprises have expressed their interest in the primary research. On analysis, the major outcomes of the primary survey are as follows:

1 Company Performance: 75 percent of the respondents felt their company performance is satisfactory / Average in the last three years.

2 Capacity Utilization: Near about 25 percent of the respondents said their plants were running at capacity utilizations of more than 60 percent (these are the companies in the large scale sector) while 25 percent of the respondents said there plants were running at capacity utilization of 60 percent. Near about 25 percent of the respondents have said that their plants were running at capacity utilizations of less than 25 percent while rest of the respondents replied that their plants were running at capacity utilization of 25 -50%.

3 Demand Outlook for the company: Near about 50 percent of the respondents felt that the demand outlook for the Nepal pharmaceutical

Industry is average and 37.5 percent of the respondents felt the demand outlook was very good.

4 Access to finance: Near about 50 percent of the respondents felt that access to finance is not a bottle neck to the Pharmaceutical industry while 37.5 percent of the respondents felt that there is a bottle neck for access to finance.

5 Research & Development: 50 percent of the respondents replied that they are investing in the research & development while rest of them is not investing into R&D.

6 Demand Outlook for the Industry: 50 percent of the survey respondents have felt that the demand outlook for the pharmaceutical industry is between 16 -20 percent. Near about 25 percent of the respondents have felt that the outlook is more than 25 percent.

7 Reasons for Foreign Players Success in the Market: The survey found that all the respondents have felt that the prices, technical know- how & broader product portfolio are the main areas where the domestic companies are facing competition from foreign players in the market. Only 12.5 percent of the respondents felt that economies of scale and quality drugs are the areas where they are facing competition from the foreign players in the market.

8 Impact of WTO: 50 percent of the respondents were indecisive on the impact of WTO on the Nepal Pharmaceutical Industry while 37.5 percent of the respondents felt that there is an impact of WTO on the pharmaceutical industry and the scenario is bleak.

9 Threats to the Industry: 50 percent of the respondents feel that cut throat competition and unfair competition is a major threat to the industry. The other factors the industry are worried are lack of technical expertise, law & order situation and the government policies.

10 Support from the government: Almost all the respondents feel that the support from the government should facilitate the growth of the industry. The major areas they felt wherein the government should come out with a grant assistance are Technology transfer assistance, financial assistance in

terms of soft loans and subsidies, setting up a world class research laboratory, Export promotion by providing necessary logistics, infrastructure facilities and increasing the output from the educational institutes.

2.6 Critical Success Factors

The critical success factors for pharmaceutical industries are:

- Marketing and Promotional Activities
- Quality of Products
- Broader Product Portfolio
- WHO-GMP Certification of Plant Facilities and Quality Management System
- Capability to Cater Domestic Market
- Economies of Scale
- Research and Development

Based on the information, it is hard to isolate success factors individually as the critical success factors for Nepalese pharmaceutical, but the above success factors in combination could be identified as success factors for the industries:

2.6.1 Marketing and Promotional Activities

Nepal's pharmaceutical market has higher per capita of brands and it is a challenging task for the marketing people to promote the products and establish its recall value in the market. Information on drugs to doctors, who prescribe the pharmaceutical products, is provided in different ways. Most of the specialists and the general practitioners don't have time or sped time to keep themselves abreast with the latest drug developments and therefore place a high value on the interactions with the medical representatives for the latest product updates. For the drug companies the first few months following the drug launches are crucial for promotion as during this period most of the companies try to establish a market for the drug. Therefore, information about the product is an essential element of a successful pharmaceutical business. Nepalese industries depending on the specialist and general practioners could be more successful in promoting their

products through this approach. The other promotional approaches are advertising, journal articles and supplements, magazines and other media outlets.

Globally the pharmaceutical industry is spending between 15 to 30 per cent of their revenues in the pharmaceutical marketing and promotions. The percentage varies and could be in the higher range for a research based pharmaceutical company while for the generic companies it is around 15 to 20 per cent. Although the spending on the marketing and promotional activities by Nepalese pharmaceutical industries is at the same level to that of Indian ones, Nepalese industries have been able to substitute Indian products and also increase their market share gradually.

2.6.2 Quality of Products

A good quality product along with gradual rise in need of quality assurance amongst industries is one of the core success factors.

2.6.3 Broader Product Portfolio

Having a broader portfolio of the products but not the me-too products helps the companies in leveraging the existing resources and the companies can be competitive in terms of costs and marketing. It brings in diversification of revenue streams. Nepal pharmaceutical industries have greater presence in anti-infective, respiratory, nutrient deficiency gastro-intestinal; anti-inflammatory/analgesics segments and dermatological segments, and such presence have led the industries to their success.

2.6.4 Possession International Certification

Possession of WHO-GMP certification of plant facilities and quality management system (ISO) has ascertained the quality of the products and has been a success factor for industries. The result of certification has driven other industries without certification to opt for certification.

2.6.5 Capability to Cater Market

Pharmaceutical industries have acquired a good knowledge about domestic market including interior and micro-interior enabling it to enhance its agility. This along with other tangible and intangible capabilities of Nepalese industries has enabled the industries to cater the market effectively and also increase market share

gradually. The agility is due to availability of qualified human resources and being private sector participation in industries.

2.6.6 Economies of Scale

The capacity utilization of Nepalese pharmaceutical industries in general is fairly low compared to that of the companies which are exporting to Nepal. Despite it, a few large industries having relatively higher capacity utilization are having their success due to their capacity utilization. Such economy of scale is being attained by those industries with higher capacity utilization of their plants by having broader product portfolio.

2.6.7 Research and Development

Research and development is critical for a pharmaceutical industry, because it leads the industry to its sustainability and future growth. Research and Development in necessary for both the industries whether research based pharmaceutical or formulation pharmaceutical industries. Some Nepalese industries undertaking manufacturing R & D are having broad product range and are successful in the market. It is one of the core factors for their success.

3. WORLD TRADE ORGANIZATION

World Trade Organization (WTO) was established during the Marrakesh ministerial meeting in April 1994. WTO has 148 members as on February 16, 2005. WTO provides the common institutional framework for the conduct of trade relations among its members in matters related to agreements and associated legal instruments and acts as an umbrella for the following agreements. Those are:

i. Multilateral Agreements on Trade in Goods

- General Agreement on Tariffs And Trade 1994
- Agreement on Agriculture
- Agreement on The Application Of Sanitary And Phytosanitary Measures
- Agreement on Textiles And Clothing
- Agreement on Technical Barriers To Trade
- Agreement on Trade-Related Investment Measures
- Agreement on Implementation of Article VI of The General Agreement on Tariffs and Trade 1994
- Agreement on Implementation of Article VII of The General Agreement on Tariffs and Trade 1994
- Agreement on Pre-Shipment Inspection
- Agreement on Rules of Origin
- Agreement on Import Licensing Procedures
- Agreement on Subsidies and Countervailing Measures
- Agreement on Safeguards

ii. General Agreement on Trade in Services

iii. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

iv. Understanding on Rules and Procedures Governing the Settlement of Disputes

v. Trade Policy Review Mechanism

vi. Plurilateral Agreements

- Agreement on Trade In Civil Aircraft
- Agreement on Government Procurement
- International Dairy Agreement
- International Bovine Meat Agreement

Plurilateral agreements are for those members that have accepted them, and are binding on those members only and do not create obligations or rights for members that have not accepted them.

A member who accepts the WTO agreement should enforce or implement those concessions and obligations in the multilateral trade agreements. The agreements which have an impact on the pharmaceutical industry are:

i. General Agreement on Tariffs And Trade 1994
ii. Agreement on Technical Barriers to Trade
iii. Agreement on Trade Related Aspects of Intellectual Property Rights
iv. Agreement on The Application of Sanitary and Phytosanitary Measures

3.1 Provisions affecting Pharmaceutical Industry

3.1.1 General Agreement on Tariffs and Trade 1994

The General Agreement on Tariffs and Trade is based on the commercial policy provisions contained in specific chapters of the Havana Charter and was the basis for establishing the International Trade Organization in 1948. For over fifty years, the GATT system has provided the framework for the conduct of trade relations, and played an important role in creating the preconditions for liberalization through eight rounds of multilateral trade negotiations. The eighth round (Uruguay round market access deal) called Marrakesh protocol has come out with an agreement to completely eliminate tariff barriers in nine industrial sectors of paper, from pulp to all forms of made up paper articles, steel, pharmaceuticals including finished medications of all forms, construction equipment, agricultural equipment, medical equipment, office furniture, toys, whiskies, brandies and beer. The pharmaceutical sector includes all intermediates used for production of pharmaceuticals as well as pharmaceuticals themselves including over- the-counter medicaments, all will be brought under the zero-tariff rule.

The second paragraph of the Marrakesh Protocol (1993) to the General Agreement on Tariffs and Trade 1994 specifies that the tariff reductions agreed upon by each member will be implemented in five equal rate reductions, except as otherwise specified in a Members schedule to the Marrakesh protocol. The schedule annexed to this Protocol relating to a Member is considered as Schedule to GATT 1994 relating to that Member on the day on which the WTO Agreement enters into force for that Member. As per the Marrakesh protocol, the tariff reduction will begin on January 1 1995. Tariffs for goods like pharmaceuticals would be eliminated in one step on January 1 1995. For the other sectors the reduction will be phased in a period of over 10 years.

3.1.2 Agreement on Technical Barriers to Trade

Among all the industries, the pharmaceutical industry is the one which is highly regulated across the globe with good number of technical measures required to be adhered to by the producers or marketers of the drugs across the territories. This is further complicated by the multiplicity of the regulatory agencies around the globe and the wide variations in the technical parameters of the regulating agencies. The Agreement on Technical Barriers to Trade tries to bring in the transparency in the framing of the regulatory standards and assessment procedures of the member countries so that the trade is not restricted among the members of the WTO.

Article 2.8, 2.9 & 2.11 of Agreement on Technical Barriers to Trade stipulates that the importing country can specify technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics. Here the requirements like product characteristics, related processes and production methods including the applicable administrative provisions which the exporting company has to comply. The Article 2.9 specifies that for any change in the regulations for the compliance of the product, the importing country can come out with a new or appended regulation which the exporting companies or members has to adhere. As per Article 2.11 the importing country can direct the other members to get acquainted with the new regulation. This provision gains significance in the case of the bio-pharmaceutical products wherein one can manufacture the biotech products through various means/processes and for every different process of making one has to get the

complete regulatory approvals which increases the time and costs of approval. This would be a restriction for trade on the grounds of safety & health aspects.

Article 5, on conformity with the technical regulations and standards deals with the conformity assessment procedures which are prepared, adopted and applied so as to grant access to the suppliers of similar products originating from the territories of the other member countries.

3.1.3 Trade Related Aspects of Intellectual Property Rights

Among all the agreements of the WTO, the agreement which has gained prominence and generated concern regarding the pharmaceutical industry is the Trade Related Aspects of Intellectual Property Rights.

The WTO's agreement on Trade Related Aspects of Intellectual Property Rights tries to strike a balance between the long-term objective of providing incentives for future inventions and innovations, and short term objectives of allowing people to use existing inventions and innovations. The agreement deals with a wide range of subjects, starting from copyright and trade marks, to integrated circuit designs and trade secrets. Patents for pharmaceuticals and other products are only a part of the agreement.

This agreement of the TRIPS has tried to strike a balance in the following three areas:

i. Invention and creativity are necessary for social and technological benefits. Intellectual property protection supports the inventors and creators in earning some future benefits out of their creativity. This encourages development of new drugs with high investments and risks.

ii. Protection of the patents also benefits society as disclosures of the inventions allow others to study the invention even while the product is still in the patent period. Thus it allows the progress, dissemination and transfer of technology.

iii. The government's role in increasing the standards of public health may requires it to violate the patents in the event of national emergencies, anti-competitive practices or if the right holder doesn't supply the invention, etc.

The TRIPS agreement has factored in such scenarios and has come out with the conditions when the patents can be violated.

The articles or the provisions of the TRIPS that affects the pharmaceutical industry are Article 27, Article 33 and the Article 39. The Article 27 deals with the protection of the patents and the Article 33 deals with the duration of the patent protection. Article 39 deals with the protection of the undisclosed data that is submitted during the marketing approval of the pharmaceutical products by the companies. The other standard concerning the availability, scope and use of the Intellectual Property Rights that is technically related with the pharmaceutical industry and of least importance in the running of the business is the Trademarks, as given in the Article 15 and Article 16. The importance of this to the industry is very little as the players usually don't indulge in trade mark violations, because marketing of pharmaceutical product is highly regulated in all most all countries

Article 27 deals with the member countries obligation of providing the protection of patents. As per this article patents should be available for any invention, whether products or processes, in all fields of technology, provided that those are new, involve an inventive step and are capable of industrial application. And moreover the members cannot discriminate on issues such as the place of invention while protecting the patents.

Article 33 provides the terms of protection. As per this article, the term of protection available should last for a period of twenty years counted from the filing date.

Article 39.3 obligates the members to protect the undisclosed tests or other data submitted for the approval for marketing of pharmaceutical products against any commercial use as the origination of data involves considerable effort. Members are to protect such data against disclosure, except in case where it is necessary to protect public interest.

Article 70.8 of the Agreement on Trade Related Aspects of Intellectual Property Rights specifies that the members should provide a means of filling the applications for patents of inventions from the date of entry into the WTO agreement. This is irrespective of the provisions of the part VI of the TRIPS agreement on Transitional Arrangements. This is sometimes called a Mailbox

provision. Exclusive marketing rights are granted for five years after approval in countries which are in a transition phase as per WTO or until a product patent is granted or rejected in that country , provided that a patent application was filed and granted for that product in another member country, and marketing approval is obtained.

Exceptions for the Grant of Patents

The following are the exceptions that are allowed by the various member countries in rejecting or refusing the grant of patents as per the TRIPS agreement:

a. Eligibility for Patenting or Patentability

The members can exclude patentability of the inventions, if it considers the prevention of patentability within their territory for commercial exploitation if it is necessary to protect public order or morality, including protecting human, animal or plant life or health or to avoid serious harm to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

Members may also exclude from patentability:

Diagnostic, therapeutic and surgical methods for the treatment of human or animals.

Plants and animals other than micro-organisms, biological processes for the production of plants or animals other than non-biological and microbiological processes.

b. Bolar Provision

Many countries use this provision as per Article 30 as exceptions to rights conferred to support the advancement of science and technology. This allows the researchers to understand the patented invention more thoroughly. Some of the countries are using this provision to allow the generic producers to manufacture the drug without the patent holder's permission to get an authorization for marketing of the drug once the product looses patent.

c. Anti-Competitive Practice

The members can take appropriate measures which are consistent with the provisions of the TRIPS agreement to prevent the abuse of the intellectual property rights by right holders or practices which unreasonably restrain the trade or adversely affect the international transfer of technology as per Article 8 and Article 40 of the TRIPS agreement.

d. Compulsory Licensing

Compulsory licensing is the provision to be used in case of national emergencies and to address anti-competitive practices, when the member country uses the law to allow the use of the patented subject by any party other than the right holder of the patent. The party can be the government itself or the party authorized by the government. As per Article 31 of the TRIPS, use without the authorization of the right holder should be granted by considering the following provisions:

Such use is permissible only if the other user has approached the right holder of the patent on reasonable commercial terms and conditions and the efforts are not successful within a reasonable period of time. In case of a national emergency or circumstances of extreme urgency or in cases of public non-commercial use the government can wave the above requirement.

The grant of authorization is non-exclusive i.e. patent holder can continue to produce.

The scope and duration of such use has to be restricted to the purpose for which it was authorized.

The authorization given is for the domestic market of the member government for which it is intended. On August 30 2003, WTO members agreed on legal changes to Article 31(f) to make it easier for countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines themselves.

The right holder of the patent has to be given the appropriate remuneration in such cases taking into account the economic value of the authorization.

The legal validity of the decision on the remuneration to be paid will be in the territory of the member country only.

e. Parallel Imports, Grey Imports and Exhaustion of Rights

Parallel or grey market imports are the products that are marketed by the patent holder or the licensee from the patent holder in two different markets and importing to the other country without the prior permission of the patent holder. This is significant as the prices of the products in the two markets can vary and movement of the products from the low priced markets to the high priced market would eventually erode the margins for the patent holder.

The TRIPS agreement doesn't have any provisions other than the non-discrimination to address this issue of exhaustion (it is the idea that once the company sold a batch of its products, its patent rights are exhausted on that batch and it no longer has any rights over what happens to that batch) of intellectual property rights in a WTO dispute as per Article 6 of the TRIPS.

3.1.4 Agreement on the Application of Sanitary and Phytosanitary Measures

As per the annexure A of the Agreement on the application of sanitary and Phytosanitary Measures, Sanitary or Phytosanitary measures are those steps taken to protect the life of human or animal or plant or health within the territory of the member country of the agreement from the risks arising from the spread of pests, additives, toxins, diseases or disease carrying organisms. It includes all the related laws of protection of the health, requirements and procedures, processes and production methods; testing, inspection, certification and approval procedures, quarantine treatments including relevant requirements associated with the transport of animals or plants, with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment, packaging and labeling requirements that are directly related with food safety.

Article 2 of the Basic Rights and Obligations of the Agreement on the application of Sanitary and Phytosanitary measures gives the rights and the obligations that the members have for the sanitary and phytosanitary measures.

4. PROVISIONS / FLEXIBILITIES OF TRIPS FOR LDC'S

The Article 65, Article 66 and Article 67 of the TRIPS give the provisions for the member countries for enforcing the WTO agreements. The provisions are given through these articles as the members are in the process of transformation from a centrally planned into a free-enterprise economy and which is making structural reforms to its intellectual property rights system.

Article 66 of the TRIPS gives the provisions for the least developed country members a period of 10 years from the date coming into force of the application to the WTO. This provision is given based on the economic, financial and administrative constraints and the need for flexibility of the least developed countries to create a viable technological base. Some of the members of the group (mainly the African members of the WTO) have pushed for the clarifications on these flexibilities given in TRIPS agreement which would allow the member nations to utilize in a way that supports the public health based on the apprehensions of the holding their rights/concerns when needed at the Doha ministerial conference in November 2001. As a result of this in the main Doha Ministerial Declaration of November 14 2001, the members of the WTO felt the need to look at TRIPS agreement in terms of supporting the public health by promoting access to existing medicines and creation of new medicines and adopted a separate declaration on TRIPS and Public Health.

The ministerial conference underplayed the Least Developed Countries abilities to use the flexibilities that are built into the TRIPS agreement like the compulsory licensing and the parallel imports for the national interests. This was referred to the council of TRIPS. The council of TRIPS on June 27 2002 has decided that the Least Developed Countries needn't oblige the standards of patents and the protection of undisclosed information for the pharmaceutical products until January 1, 2016. The list of Least Developed Countries is given in Appendix 4.1..

5. EFFECT OF WTO ON NEPAL'S PHARMACEUTICAL INDUSTRY

The impact of WTO on Nepal's pharmaceutical industry can be identified by studying the affect of each agreement of WTO that has impact on the pharmaceutical industry.

5.1 TRIPS

The main impact of TRIPS agreement of WTO will be felt on two areas. They are:

1. Domestic manufacturers who are producing and commercializing products covered by patents will be forced to go for licensing agreements with the patent holders resulting in the royalty payments and in some situations there would be an increase in prices of the drugs.

   By the time Nepal recognizes the patents of products related to the pharmaceutical industry, most of the drugs that were approved for marketing from 2002 would be still in patent period as on January 1, 2016. For these drugs either the innovators will distribute these drugs themselves through his own distribution channels or give license for the players who are operating in the domestic market by charging a royalty on the sales. As per the mail box provision of TRIPS, the patent holder has to file his application for patent in the Nepal market with the concerned regulatory agency in order to get patents recognized in the market. On adhering to the applications that are filed for recognition of patents as given in the mail box, there would be withdrawal of some of the brands belonging to the domestic players from the market drugs which are still in patent period. The following are the list of the drugs that are approved by USFDA from 2002 is given in the Table No. 5.1:

Table No. 5.1: Molecules Approved by USFDA, 2002 - 2005

S. No	Proprietary Name	Established Name	Applicant	Approval Date
1	Symlin	Pramlintide Acetate	Amylin	16-Mae-05
2	Mycamine	Micafungin Sodium	Fujisawa	16-Mae-05
3	Baraclude	Entecavir	Bristol Myers Squibb	29-Mae-05
4	Byetta	Exenatide	Amylin	28-Apr-05

5	Tygacil	Tigecycline	Wyeth Pharms	15-Jun-05
6	Levemir	Insulin Detemir	Novo Nordisk	16-Jun-05
7	Aptivus	Tipranavir	Boehringer Ingelheim	22-Jun-05
8	Spiriva Handihaler	Tiotropium Bromide	Boehringer Ingelheim	30-Jan-04
9	Alimta	Pemetrexed Disodium	Eli Lilly	4-Feb-04
10	Sensipar	Cinacalcet Hydrochloride	Amgen	8-Mar-04
11	Ketek	Telithromycin	Aventis Pharms	1-Apr-04
12	Human Secretin	Human secretin	Chirhoclin	9-Apr-04
13	Apidra	Insulin Glulisine	Aventis Pharms	16-Apr-04
14	Apokyn	Apomorphine Hydrochloride	Bertek	20-Apr-04
15	Vitrase	Insulin Glulisine	Aventis Pharms	5-May-04
16	Tindamax	Tinidazole	Presutti Labs	17-May-04
17	Vidaza	Azacitidine	Pharmion	19-May-04
18	Xifaxan	Rifaximin	Salix Pharma	25-May-04
19	Sanctura	Trospium Chloride	Indevus	28-May-04
20	NutreStore	L-Glutamine	Nutritional Restart	10-Jun-04
21	Campral	Acamprosate Calcium	Lipha	29-Jul-04
22	Cymbalta	Duloxetine Hydrochloride	Eli Lilly	11-Aug-04
23	Pentetate Zine Trisodium	Pentetate Zine Trisodium	Pharma Hameln GmbH	11-Aug-04
24	Pentetate Calcium Trisodium	Pentetate Calcium Trisodium	Pharma Hameln GmbH	11-Aug-04
25	Fosrenol	Lanthanum Carbonate Hydrate	Shire Pharm	26-Oct-04
26	Amphadase	Hyaluronidase	Amphastar Pharm	26-Oct-04
27	Omacor	Omega-3-acid Ethyl Esters	Ross Prods	10-Nov-04
28	Tarceva	Erlotinib Hydrochloride	OSI Pharms	18-Nov-04
29	VESIcare	Solifenacin Succinate	Yamanouchi	19-Nov-04
30	Multihance	Gadobenate Dimeglumine	Bracco	23-Nov-04
31	Enfuvirtide	Fuzeon	Roche	3/13/2003
32	Pegvisomant	Somavert	Pharmacia and Upjohn	3/25/2003
33	Aprepitant	Emend	Merck	3/26/2003

34	Gemifloxacin Mesylate	Factive	LG Life	4/4/2003
35	Gefitinib	Iressa	AstraZeneca	5/5/2003
36	Bortezomib	Velcade	Millennium Pharms	5/13/2003
37	Ibandronate Sodium	Boniva	Roche	5/16/2003
38	Alfuzosin Hydrochloride	Uroxatral	Sanofi Syn Res	6/12/2003
39	Atazanavir Sulfate	Reyataz	Bristol Myers Squibb	6/20/2003
40	Emtricitabine	Emtriva	Gilead	7/2/2003
41	Palonosetron Hydrochloride	Aloxi	Helsinn Hlthcare	7/25/2003
42	Miglustat	Zzvesca	Actelion Pharms	7/31/2003
43	Rosuvastatin Calcium	Crestor	AstraZeneca	8/12/2003
44	Vardenafil Hydrochloride	Levitra	Bayer Pharms	8/19/2003
45	Daptomycin	Cubicin	Cubist	9/12/2003
46	Prussian Blue	Radiogardase	Fabrik GmbH Heyl Chemisch-Pharmazeutische	10/2/2003
47	Memantine Hydrochloride	Namenda	Forest Labs	10/16/2003
48	Epinastine Hydrochloride	Elestat	Allergan	10/16/2003
49	Tadalafil	Cialis	Lilly Icos	11/21/2003
50	Abarelix	Plenaxis	Praecis	11/25/2003
51	Sertaconazole Nitrate	Ertaczo	Mylan Pharms	12/10/2003
52	Nitisinone	Orfadin	Swedish Orphan	1/18/2002
53	Olmesartan Medoxomil	Benicar	Sankyo	4/25/2002
54	Fulvestrant	Faslodex	AstraZeneca	4/25/2002
55	Treprostinil Sodium	Remodulin	United Therapeutics	5/21/2002
56	Voriconazole	VFEND	Pfizer	5/24/2002
57	Dimyristoylphosphati Dylcholine Perflexane	Imagent Kit for the Preparation of Perflexane Lipid Microspheres	Alliance Pharm	5/31/2002
58	Sodium Oxybate	Xyrem	Orphan Medical	7/17/2002
59	Tegaserod Maleate	Zelnorm	Novartis	7/24/2002
60	Oraliplatin	Eloxatin	Sanofi	8/9/2002

61	Adefovir Dipivoxil	HEPSERA	Gilead	9/20/2002
62	Eplerenone	Inspra	GD Searle	9/27/2002
63	Ezetimibe	Zetia	MSP Singapore	10/25/2002
64	Aripiprazole	Abilify	Otsuka	11/15/2002
65	Nitazoxanide	Alinia	Romark	11/22/2002
66	Atomoxetine Hydrochloride	Strattera	Lilly	11/26/2002
67	Icodextrin	Extraneal	Baxter Healthcare	12/20/2002

Source: Cygnus Research

A break through drug in a particular therapeutic segment would completely direct all the prescriptions towards the new drug as other drugs are not as effective. This would lead to monopoly in pricing for the innovator.

Consider the case from antibiotic segment. Agent causing disease in peoples develops resistance to antibiotics on long usage and thus there is need for newer versions of the antibiotics. Nepalese are more prone to infective diseases compared to those in the western countries and as a result consume higher proportions of antibiotics. This results in faster development of resistance to antibiotics and the condition recommends for the newer versions of antibiotic drugs with shorter delays compared to westerners. It was also found in one of the studies that the 90 per cent of the people in US will be responding to the first generation antibiotics but it is not the case with the people living in the south Asia like India where only 10 per cent of the people will respond to the first generation antibiotics. If an innovator comes out with a new antibiotic and if it proves to be exceptionally good in therapeutic usage then the innovator will be demanding a monopoly price in the market where patents are recognized.

Most of the essential drugs that are listed by DDA, Nepal are out of patent period. It is not that the drugs that will be approved in the next 10 years would be completely dominating the therapeutic segments into which they are. This is quiet evident from the study that was conducted during July 2001 by Public Citizen (a US based nonprofit consumer advocacy organization founded in 1971) which has found that only about 22 per cent of the new drugs that were brought into the market in the last two decades were critically important with innovative therapeutic advances. But in the situations like that there would be a general increase in prices

of the drugs compared to a non-patent recognized market. On the other hand for development of the country in the areas of science & technology and rewarding the risks taken to research would help the pharmaceutical industry, as Asian countries have cost advantages compared to the western countries. Moreover the governments have the right of using the compulsory licensing provision of the TRIPS in national interest. This is how the drugs manufactured by Indian players were given the permission to market the HIV drugs in the South African market as they are able to provide the drugs at lower cost to combat the national endemic of HIV disease.

2. TRIPS inhibit the advantages the players are currently deriving through reverse engineering and there would be increased investments in R&D

   Here the domestic pharmaceutical companies which are currently progressing well with the generic versions of the patented drugs with lesser costs would loose the opportunity of coming out with the newer drugs within a period of 1 to 2 years from the launch of the innovator product in the international markets. So the option for them would be to remain completely a generic player or slowly move to a research based pharmaceutical company or be a contract manufacturer for the innovative and generic companies. With such scenario the business and revenue models of the pharmaceutical companies would be witnessing a change. As the options for the companies to sustain will be few, there would be increased investments in research & development by the companies and the investments would go from the current levels of less than 1 per cent of sales to near about 5 to 8 per cent by the time the patents are recognized in the pharmaceutical industry from 2016

3. With the introduction of TRIPS, most of the MNC players would be eyeing the market in a major way as the product patents are recognized and they come out with their complete portfolio of drugs which are of highest quality produced in plants that are certified by regulatory agencies globally with the economies of scale(in most of the cases the plants from which the drugs are produced for the Nepal market would be located outside until unless there is a distinct cost advantage in the domestic market and the market is so huge in 2016). Moreover with the growth of the market, there

would be tougher competition from the generic MNC's to the domestic companies. This results in the domestic players also making their drugs in the internationally certified plants to have better quality with higher capacity utilizations and increase their budgets for the marketing and promotional activities to sustain in the market.

Looking at the impact of the patent recognition of the drugs (molecules) on the pharmaceutical industry in the various market, it was found that the industry has grown overall in terms of growth, increased domestic players presence and increased Alliances/Joint ventures/ technology transfers, etc. The impact in countries such as South Korea, Mexico and China where patent laws were enforced earlier is positive (Table No.5.2).

Table No.5.2: Effect of Patent Protection

Country	Year when international compatible patent law comes into operation	Effect on country
South Korea	1986	Local firm market share increased from 87.3% (1986) to 89.2% (1990). Local firms have 75% of patent applications. Now an exporter of modern pharmaceutical technology
Mexico	1991	Tripling of investment by research-based pharmaceutical companies. Competitiveness of domestic industry enhanced by technology transfer
China	1993	17% annual growth rate for the pharmaceutical market. Number of joint venture increased.

5.2 Technological Barriers to Trade

As per the Agreement of Technological Barriers to Trade, the Articles 2.8, 2.9 & 2.11 specifying the Technical Regulations and the Article 5 dealing with the conformity assessment can be the restrictions for trade. The other issues that can be of importance with this agreement are the transparency of the regulations framed by the members, the protection of data submitted for the approval of new drugs and the granting of market access including the drug registration and re-imbursements. Currently Nepal pharmaceutical industry wouldn't face any restriction to trade

with this agreement, but this can turn into a restrictive agreement once the companies from the industry starts looking at the export markets.

Data to be provided: While adhering to the importing country's technical regulations for the product, the exporting company has to present all the information related to product, both the technical and the production quality data as per the regulations of the importing country. This demand for the data can again be problematic due to the variation in the interpretation of the science and applying it to the regulatory concerns. In this process the data that has to be submitted to the regulatory agencies or bodies widely varies. These additional requirements would further delay the entry of the product to the market and would increase the costs also. Some of the agencies would require exporters to provide vast quantities of production quality data and process data to get the marketing approval in their territory. And moreover the information or the data that is provided for the marketing approval of the drug is mostly of the results in the Phase III clinical trials. There is an acute proprietary sensitivity of the information supplied to the regulatory agencies as any instances of the leak of sensitive information would help the domestic generic drug manufacturers to produce substitutes for the product at lower costs. So there is a barrier for the research based companies in providing their product data bases to the agencies.

Testing procedures: The output of the pharmaceutical production is routinely tested for the conformity of the quality and safety regulations. This is done by the manufacturer either through his own quality check set up or through an independent testing procedure based on the regulatory agencies specifications. There are instances where some of the regulatory agencies demanded costly and redundant testing procedures to raise the effective barriers to imports. The biggest loss for a pharmaceutical company is the time lost between the initial launch of the drug and before it is offered for sales.

Added to this are the differences in the regulations for the biological products across the countries and it would pose challenge for the companies to get the approval. For example New Zealand has taken a genetically modified vaccine off the market as it is administered orally and it is manufactured from a genetically modified organism. The country feels that the administered vaccine orally would find some traces while it is excreted in the environment. Moreover for these

biological products, the companies should demonstrate that there is no breakage of the cold chain of distribution between the manufacturer, transporter, distributor and the end-point use. Here the shelf life issues are of concern. Here the presence of the large number of regulatory issues like policy decisions, quality standards, monitoring, etc would further leave room for the delays on the grounds of technological barriers for trade.

5.3 Agreement on the Application of Sanitary and Phytosanitary Measures

As per the Sanitary and Phytosanitary measures, export potential of the pharmaceutical firms in the Least Development Countries will be hindered as most of the production plants in these countries are not in compliance with the Agreement on the applications of Sanitary and Phytosanitary Measures. Pharmaceutical companies has to follow current Good Manufacturing Practices as determined by WHO which needs much of the investments into the production plant which most of the pharmaceutical companies in the LDC's like Nepal are not in a position to invest. But the production plant has to confer to the national standards, rules. The national rules standards have to confer to the SPS agreement.

6. STEPS TO ENHANCE COMPETITIVENESS

Competitiveness of a sector or industries under the sector can be enhanced through the enhancement of quality and productivity of the sector or its industries. Therefore, the steps to be taken by the Nepalese pharmaceutical industries to enable them to capitalize on the opportunities and face up to the challenges would be those measures, which would enhance quality and productivity of the industries in isolation or in combination. The steps are as follows:

6.1 Quality Enhancement:

6.1.1 Quality Assurance of Products through Plant Facility Certification

WHO-GMP certification ensures the quality of plant facilities and pharmaceutical products produced at the plant. Such assurance develops trust of the medical doctors as well as general practioners and end customers on pharmaceutical products, and this ultimately assist in capturing the domestic and export markets. Presently five industries have WHO-GMP Certification and do have good market recognition and are doing good business. A significant number of industries are under going through the certification process. One of the considerations medical doctors take while prescribing foreign or domestic brands is the quality of medicines. By assuring the quality products domestic industries can overcome the biasness and apprehensions usually associated with them, this could result in increased prescriptions from medical professionals. As the quality certification opens-up the door to international markets and domestic markets, the industries having certification would be more competitive. The Nepalese industries with quality assured product can expand their business in domestic market at first and then enter export markets.

6.1.2 Quality Assurance through Quality Management System and Environment Management Systems

Having ISO 9001:2000 Series and ISO 14000 Certification will not only improve the corporate image of the industries but also guide the industry to have management systems which could lead them to their long term sustainability and growth; and fulfill the environmental responsibilities. These certifications can also assist industries to have systems, procedures, data/information base and others

where these are lacking especially in industries run and managed by owner-managers leading to enhancement in quality, productivity and competitiveness.

6.1.3 Adoption of Stringent Quality Standards

Quality assurance is possible by improving quality assurance systems of industries and it could be carried out without any certification. Nepalese industries need adopt measures for quality assurance and adopt stringent quality standards. This could restrict unfair competition in domestic market from the low quality producers by pressurizing and assist the Government in regulating quality control measures and thus minimize the unfair competition from low quality products of both domestic and foreign industries.

6.2 Enhancing Productivity

6.2.1 Enhancing Productivity by Attaining Economy of Scale/Efficiency

Attainment of economies of scale by industries helps in enhancing their productivity, which is possible through various measures. These measures, which in isolation or in combination could lead those industries to attain their economies of scale, are:

a. Higher Capacity Utilization

The capacity utilization of Nepalese industries varies from 25% to 80% depending upon investment scale and others. Small scale industries have capacity utilization of 25 to 40%, medium scale 40 to 60% and large scale above 60 percent. Small and medium scale industries need to increase their capacity utilizations by rationalizing the product mix and even outsourcing to the large scale industries for the benefit of both. Increased capacity utilizations bring better utilization of physical resources to the industries and bring better margins; if products having market potential could be produced. The industries having export potential could look for export markets in order to grab foreign market and to increase their capacity utilization. Especially, the large scale industries having WHO-GMP certification(s) and operating at higher than 80% may look to the international markets for exports apart from increasing the domestic market share. The first step towards this will be to identify the LDCs, where the WHO-GMP practices are sufficient for exports. After possessing an

"investible surplus" from those markets, the industries may explore to get their plants approved by agencies in regulated markets like USA, Japan, Germany, France, etc. With the option of the export income, income generating sources for the companies will increase and dependence on the domestic market will come down enabling the company to hold out in times of fluctuations in the market.

b. Increase Breadth of Product Portfolios

The industries could attain operational economies of scale by increasing the breadth of their product portfolios. Only a few industries are producing medicines to life style relating diseases like cardiac, CNS, diabetic, ophthalmology, etc. Therefore, there exists demand for such products and efforts need to be made by other industries to produce those pharmaceuticals by fulfilling the pre-requisites for their production, if possible. It is because these are the segments, demand for which is growing faster and lasts for longer period.

c. Acquire Technical Manpower

The industries could attain their economies of scale by developing human resources either by providing opportunities to its personnel or recruiting new ones, if the limitation is due to the constraint of highly skilled technical personnel. With the personnel of that nature Nepalese industries could initiate process of reverse engineering and chemical synthesis.

d. Increase Share in Domestic Market

Currently, imports account for about 70% of the domestic market and the share of the domestic industries is only about 30%, which needs to be increased. With the increase in sales and market share, industries could optimize the use of their plants.

6.2.2 Enhancing Productivity by Reduction in Cost of Production

a. Efficient Utilization of Inputs

Productivity of pharmaceutical industries could be improved with the betterment in utilization of inputs like ingredients, utilities, labour and others. This could also result in wastage minimization in industries. The

cost savings made by these would definitely enhance the competitiveness of industries.

b. Supply-Chain Management

By having effective and efficient supply-chain management industries could reduce their cost of production enhance productivity and competitiveness.

c. Backward Integration

Producing the bulk drugs or active pharmaceutical ingredients by domestic industries by acquiring the process development knowledge and skills could reduce the cost of those materials leading to drop in cost of production for industries. Such producers could look at supplying to the other domestic formulation manufacturers apart from their in-house consumption. Apart from domestic market, there could be an export potential for those with the certified plant. This brings in better margins for the companies by integrating operations backward. The purposes of such integration is to achieve control on costs, quality and delivery period of inputs.

d. Common Infrastructure and Facilities

Having common infrastructure and facilities could also reduce in cost of production and waste disposal leading to the improvement in productivity and then to competitiveness of industries using common infrastructure and facilities. It is because majority of Nepalese pharmaceutical industries are small and medium scale having limited investment capabilities.

6.2.3 Enhancing Effectiveness

a. Marketing and Promotions

The industries need to be aggressive in marketing and employ innovative marketing strategies and promotional measures to counter the well established foreign companies. Sales and the marketing representatives have to adopt a professional approach, for which regular training and up-gradation of sales forces and medical representatives will be necessary. The number of field visits of the medical representatives need to be optimized

for better coverage of the doctors, which in turn will augment the demand through increased prescriptions.

b. Explore Export Markets

Looking at the export market is vital for the Nepalese industries as the domestic market is small compared to world market. The industries could explore the opportunities of exporting formulated products and active pharmaceutical ingredients, if produced. This can be started with the neighboring markets of Bangladesh and other LDCs. To capture these opportunities the plants should be upgraded to international standards. As the large industries have already the WHO-GMP certified plants those could look towards export markets. The major constraint for exports is the need for airlifting of products for industries, which is affecting in their competitiveness. Therefore, efforts need to be made to solve by appealing to the government and garnering required assistance to make exports competitive.

c. Increase Linkages with the Academia

There is an urgent need for the domestic companies to interact with the academia or the research institutions in the country to utilize their resources productively for the development of better process of manufacturing through qualified technical manpower with the good expertise in fields related to pharmacy. This to a greater extent can also overcome the constraint of technical manpower along with the sharing of the costs.

d. Increase Work Relationship with Professional and Business Associations

With a view to enhance the effectiveness of business, industries need to develop, review and maintain work relationships with professional associations like NMA, and business/trade associations FNCCI, APPON, NCDA, etc. These could influence the doctors to prescribe the drugs for which the domestic brands are available. The pharmaceutical sector as a whole needs to address this issue and communicate the message to the doctors. This kind of work relations could publicize Nepalese

pharmaceutical products. A strong franchise developed with the doctors and the chemists could avoid substitution of pharmaceuticals.

6.2.4 Competitiveness through Innovation

a. Undertaking Innovative Research and Development

Investment in research & development of pharmaceuticals by Nepalese industry is relatively very low; less than one percent of the total sales. The industry could enhance its competitiveness by investing in R&D, mainly into organic synthesis for the reverse engineering of the molecules and minimizing the number of steps in the manufacture of the bulk drugs and final products. The increased capability in the reverse engineering of the molecules could gradually lead to the expertise in molecule research. It could improve their long term sustainability either through contract research or cost effective products with vibrant in-house R&D.

b. Institutionalization of Industries

Gradual institutionalization of Nepalese industries would be necessary for enhancing the competitiveness of the sector as a whole. It would provide vision and mission for the industries, where those should head for and also organizational systems, procedures, processes, and others. A few industries might have to under go even restructuring and reengineering processes.

c. Collaboration

Collaboration with foreign or domestic companies could enhance competitiveness due to improvement in productivity and quality of self or due to comparative advantages of collaborating partner(s).

7. CONCLUSION AND RECOMMENDATIONS

7.1 Conclusion

Accession of Nepal to WTO has brought both opportunities and challenges to Nepalese pharmaceutical industries. World market of pharmaceutical products is now open to Nepalese industries and simultaneously Nepalese market is open to industries worldwide. In this context Nepalese pharmaceutical industries need to be able to explore the opportunities and make best use of those. In addition, those industries also need to identify the external threats for them and make efforts to overcome the threats. Therefore, Nepalese pharmaceutical industries have to undertake measures that would enhance their competitiveness, which could lead them to harness their strengths for exploiting the opportunities before stepping into WTO/TRIPS regime in 2016. Since competitiveness of industries under the sector could be enhanced through the enhancement of quality and productivity of the industries, the measures to be taken in isolation or in combination by the Nepalese pharmaceutical industries would be to enhance quality and productivity of the industries which would enable them to capitalize on the opportunities and face up to the challenges. Based on the study of present status; and analyses of opportunities and challenges for Nepalese pharmaceutical industries in the wake of WTO, recommendations are made for government, private sector industries, and associations related to pharmaceutical industry for enhancing the competitiveness of pharmaceutical industries.

7.2. Recommendations

7.2.1 Government

a. Introduction and Implementation of Act, Policies, Programmes

The government has introduced act, regulations and others relating to establishment, development, promotion and regulation of pharmaceutical industries; some of which are still to be implemented for attaining their objectives. Therefore, government should implement those. In addition government should amend acts and regulations making those compatible with WTO requirements (e.g. As per WTO requirement patent should be granted for a period of 20 years but Patent, Design and Trademark Act of Nepal and its recent amendment grant patent for a period of 7 years only

which can be renewed 2 times for a period of 7 years each). The government should also amend foreign investment and technology transfer act making it attractive for foreign direct investment in pharmaceutical sector for research based pharmaceutical industry.

b. Establishing Promoting and Facilitating Institution

i) Research Institutions

Since majorities industries are of small and medium scale, those can not take certain functions of their own and therefore, the government should encourage establishing institution(s) to carry out such functions private sector or under public – private partnership arrangements for the development of the domestic pharmaceutical industries. For example, the government should encourage establishing a quality research & development laboratory of state of art for those industries, which will be a model for the private companies of large scale to go for. The institution should encourage interaction amongst the government, academia and industry in the areas of process reverse engineering, synthetic chemistry, etc. The government should encourage also capacitate these laboratories to function as technology assisting centres for the industry.

ii) Areas with Common Infrastructural Facilities

The government should develop specified location /areas with common infrastructural facilities to encourage the setting-up of pharmaceutical units in a place where the facilities like common effluent treatment plant, common testing facilities, capital intensive equipments, common training facilities, etc would be readily available. Such facilities would reduce operating costs for the industries.

iii) Information Centre

Information centre for providing information on technology, export market, regulatory obligations, and sector related information for developing and promoting pharmaceutical industries should be

established by the government in association with the respective trade association by utilizing resources to be provided by developed countries as per the provision of WTO agreement.

c. Strengthening Regulatory Bodies

Government should increase the capability of the Department of Drug Administration to develop quality awareness and enforce quality requirement in the market. Currently, there is a shortage of manpower to fulfill its responsibilities limiting its area of services. It should be strengthened and provided with necessary resources to carry out regulatory and other functions. The strengthening of regulatory body will check the presence of unregistered and low quantity drugs in the market which is creating an unfair competition affecting even the genuine industries.

d. Completely Utilize Provisions of WTO

The government should utilize the assistance that would be provided by the developed countries as per the provisions of the WTO agreements in terms of the technological assistance, financial assistance and creation of the domestic regulatory environment for effective monitoring and development of the industry so that there will be a smooth transition to the WTO regime. Government should be effective in terms of using the technical barriers to trade agreement for countering the imports by introducing product label with certain information in Nepalese language to help the consumer of the products.

e. Make Alliances/Treaties with Neighbors

The Government should enter into bilateral agreements or treaties with the regional neighbors to provide free flow of pharmaceutical products from Nepal. Currently, there is a higher registration fee for the foreign companies in India in comparison to that of Nepal. The Governments should make efforts to have compatible fees, limiting its sales in adjoining states only.

f. Develop and Strengthen Health Institutions

The government health services are available to only a small portion of the population. As Health services is a basic need for all, therefore the government should develop/establish health institutions in new areas and strengthen the existing ones to provide health services to its people. The government should necessitate those institutions to consider quality as well as price of medicines while procuring

g. Provision of Incentives

In order to encourage in establishment and plant up-gradation of pharmaceutical industries in the country, the Government should provide fiscal incentives. The industries investing in research & development should be encouraged by providing the incentives for investing in R&D like tax rebate for the amount invested into R&D. Lower or even zero duty on the imports of products or machinery that are to be used in research & development should also be provided. Similarly, export incentives should be provided to the exporting industries. With a view to motivate domestic industries to promote export, Government should subsidize registration fee charged by importing country. Since there is a lack of highly skilled technical manpower, government should provide subsidy of at least 50% of the human resources development cost incurred by the industries for above purpose.

h. Extension of Time Frame

As technological base in LDCs are very low, Nepal along with other LDCs should make efforts to extend time allocated to create a viable technological base by additional ten years i.e. upto January 2026.

7.2.2 Private Sector Industries

a. Upgrade Production Facilities

Industries should continuously upgrade their production facilities to assure the quality of products and plant facilities. Industries having WHO-GMP Certification should go for quality management system and environment management system for further assurance. The rest of the industries should also get such certification(s). Up-gradation of the production facilities

would further increase the product quality and corporate image of the domestic industries, leading to increase in prescriptions by the doctors.

b. Attaining Economy of Scale

The industries should try their best to attain their economies of scale by undertaking the following in isolation or in combination:

i. Increase Capacity Utilization

The domestic pharmaceutical companies should look for improving their capacity utilization for better operating margins and profits which again can be ploughed back into the growth plans of the company like investing into process research, up gradation of the plants, etc. In order to optimize the capacity utilization, industries should try to provide outsourcing services to the other industries for the benefit of both.

ii. Broaden Product Portfolio

The industries should broaden their product portfolio in terms of range and forms instead of concentrating in me-too products only.

c. Reduction in Cost f Production

i. Efficient Utilization of Inputs

Nepalese pharmaceutical industries should improve in utilization of inputs like ingredients, utilities, labour and others. And at the same time industries should take necessary measures to reduce wastes. The pharmaceutical industries should conduct audit of inputs in regular basis to find out level of waste.

ii. Supply-Chain Management

Special consideration of supply-chain management should be made by industries to reduce cost of production introducing efficient and effective inventory management system.

iii. Backward Integration

The companies should produce bulk drugs or active pharmaceutical ingredients by acquiring the process development knowledge and

skills, if possible. In case, if it is possible to carry out in collaboration/association with others, then to produce those and explore domestic and export potential too The basic purposes behind such integration should be to achieve control on costs, quality and delivery period of inputs.

iv. Common Infrastructure and Facilities

As using common infrastructure and facilities could also reduce in cost of production and waste disposal leading to the improvement in productivity and competitiveness, industries should ask government to develop such common infrastructure and facilities.

d. Market Expansion

i. Increase Domestic Market and Market Share

The Nepalese industries should make efforts to cater domestic demand more by having broad product portfolio in terms of range and forms. Those should not only to increase sales but also and market shares. For these, industries should adopt aggressive marketing approaches and employ innovative promotional ways to counter the products of well established foreign companies and products of inferior quality having price advantages. Domestic industries will have to strongly face competition from foreign industries and multinational companies. Franchising with chemists and druggists should also be made to reduce substitution of own products by them. The market share in the domestic market should also be increased though innovative marketing of the brands of the industry in the domestic market.

ii. Tap Export Opportunities

Tapping export markets is vital for the domestic pharmaceutical companies, because Nepalese pharmaceutical market is relatively very small. Although domestic market is the immediate driver or the revenue earning market at initial stage, export market is the one providing long term sustenance and growth for a pharmaceutical industry. Since export market is very crucial for industries, those

should explore and tap export market. Those should consider of not only the formulated products but also bulk drugs. The companies should make a beginning (at least the companies in the large scale sector). These industries should first upgrade their plants to the requirements of the market they are planning to export. Then those should manufacture pharmaceuticals at a cost that would be lower than the competitive products prevailing in the international markets.

e. Research and Development

Investment in research & development (at least process research) is essential for the survival of a pharmaceutical industry, because it leads to industrial growth by introducing generic versions faster bring down the manufacturing costs. An industry with the strong reverse engineering capability could eventually transform into research based industry and could even tap the contract research market. Therefore, industries should invest in R & D.

f. Human Resources Development

Industries should continuously invest in its Human Resource Development so that those are abreast with the latest trends in the industry whether in production or research or marketing or management. At least 2 to 3 percent of the sales should be invested in human resource development.

g. Alliances/Collaboration for Competencies

The industries wherever those can attain competence and/or acquire expertise, which are needed for long term sustenance and growths with collaboration/alliance should go for it. Such alliances can be for accessing product, technology and market for the product and should bring win-win situation to both the parties.

h. Develop Linkages with the Academia

The domestic industries should develop, review and maintain linkages with the academia or the research institutions to utilize their resources for the

development of better process of manufacturing and developing human resources.

i. Develop Work Relationship with Professional and Business Associations

Industries should develop, review and maintain work relationships with professional associations like NMA, and business/trade associations FNCCI, APPON, NCDA, etc. for fulfilling their individual and group interests.

j.. Institutionalization of Industries

Nepalese industries should start institutionalization of their industries and operate with organizational systems, procedures, processes, and others.

7.2.3 Pharmaceutical Association

a. Strengthening of Associations

The role played by the associations like APPON is tremendous and crucial for the success and growth of pharmaceutical industries. It is through such facilitating bodies interests of the industries are raised for solving the issues & challenges of the industry. Therefore, APPON should be strengthened and developed as an institution supporting industries in HRD, market, technological regulatory and WTO related information.

b. Launching of HRD Programmes

In order to upgrade the capability of human resources involved in the sector, APPON should regularly organize HRD programmes on various fields.

c. Forum for Stakeholders

It should function as a forum for knowledge sharing for stakeholder for the benefits of the industries. It should start disseminating information on quality assurance, creating awareness on the WHO-GMP and facilitating the technical expertise required for adhering to the international standards of various regulatory agencies.

d. Assistance to Industries

The association should regularly assist the pharmaceutical companies in dissemination of the information like market opportunities in the domestic or export markets. It should closely work with the industries in identifying problems that are being faced by industries. Associations should act like catalysts in building the alliances among the pharmaceutical companies in the domestic market or with the foreign companies for accessing technology or products or market.

Appendix – 1.1

Questionnaire for the study of Nepal Pharmaceutical Industry

Name of the Company : _____

Address of the Company : _____

_____

Size : Small ___ Medium ____Large_____

Name of the Respondent :_____

Designation of Respondent :_____

Telephone Number :_____ Fax Number _____

Email Address :_____

I Company Perspective

1. What are the therapeutic segments the company is currently operating into?

2. What are the major products of the company?

3. How was the performance of your company in the last 3 years (Please Tick)

Capacity Utilization

	80 % and above	60 - 80 %	40 - 60 %	< 40 %
2003	☐	☐	☐	☐
2004	☐	☐	☐	☐
2005	☐	☐	☐	☐

Sales Growth

	30 % and above	20 - 30 %	10 - 20 %	< 10 %
2003	☐	☐	☐	☐
2004	☐	☐	☐	☐
2005	☐	☐	☐	☐

Profits

	10 – 20 %	5 - 10 %	0 - 5 %	- Ve
2003	☐	☐	☐	☐
2004	☐	☐	☐	☐
2005	☐	☐	☐	☐

4. What is the demand outlook for your company's products? (Please Tick)

☐ 30 % & above ☐ 20 - 30 % ☐ 10 - 20 % ☐ < 10%

5. Are there any bottlenecks to access finance?

1. Yes 2. No

If yes, Mention types of bottlenecks (Please Tick)

1. Lack of Government Support ☐ 2. Lack of Financial Institutions Support ☐

3. Higher Rates of Interest ☐ 4. Others, Pls specify

II Industry Perspective

1. What is the demand outlook for the pharmaceutical industry in Nepal for next five years?

i) Increase	1.Up to 10%	2. 11-15%	3.16-20%	4.21-25%	5.25% & above
ii)Decrease	1.Up to 10%	2. 11-15%	3.16-20%	4.21-25%	5.25% & above
iii) No Change					

2. What is the expected growth rate of the pharmaceutical industry in Nepal for next five years?

Production

i) Increase 1.Up to 10% 2. 11-15% 3.16-20% 4. 21-25% 5.25% & above

ii)Decrease 1.Up to 10% 2. 11-15% 3.16-20% 4. 21-25% 5.25% & above

iii) No Change

3. What is the extent of competition in the Industry?

Prices of the product

1. Highly competitive 2. Reasonable 3. Not very competitive

Technical know-how

1. Highly competitive 2. Reasonable 3.Not very competitive

Capability of producing the drugs

1. Largely many units are capable
2. Very few units are capable

Distribution Network (including promotional activities)

1. Highly competitive 2. Reasonable 3.Not very competitive

Competition due to Imports

1. Highly competitive 2. Reasonable 3.Not very competitive

4. In what areas do the domestic pharmaceutical companies face competition from foreign companies? Please explain the reasons for your answer.

1. Prices _____

2. Technical know how

_____

3. Type of drugs _____

4. Quality of drugs _____

5. Distribution Network _____

6. Promotional Activity _____

5. What do you think is the share of foreign player's in the pharmaceutical market in Nepal?

_____

6. What do you think are the reasons for the foreign player's success in the market?

I_____

II_____

III_____

IV_____

7. Various measures undertaken by Nepalese Pharmaceutical companies to encounter the foreign players

I_____II_____

_____

III_____

IV_____

8. What are the strengths of the Nepal Pharmaceutical Industry?

I_____

II_____

III_____

IV_____

9. What are the untapped opportunities that are available for the Nepal Pharmaceutical Industry?

I_____

II_____

10. What are the factors that are hindering the performance of the domestic pharmaceutical companies?

I_____

II_____

11. What are the threats that are being faced by the Nepal Pharmaceutical Industry?

I_____

II_____

12. What are the critical success factors for the Nepal Pharmaceutical Industry in the current scenario? (Please Tick)

1. Economic Production Facility ☐ 2. Distribution Network & Promotion ☐

3. Technological Know How ☐ 4. Diversified Product Portfolio ☐

5. Others Please Specify

13. What kind of support does the industry expect from the government of Nepal in the following areas so as to improve the performance of the industry? (Please Tick)

1. Technology assistance ☐
2. Financial assistance in setting up of the quality production plants ☐
3. Setting up / enhancement of the quality research laboratories ☐
4. Co-ordination of various departments for the orders to local units ☐
5. Support for promoting external trade ☐
6. Infrastructure facilities ☐
7. Subsidies / Tax rebates ☐
8. Any other areas ☐

14. What kind of support can the industry expect from the Pharmaceutical Producers Association for the betterment of Nepal pharmaceutical industry?

I_____

II_____

15. What do you foresee the impact of WTO on the Pharmaceutical industry in Nepal?

I_____

II_____

16. What are your suggestions to the Nepal pharmaceutical industry to gear up for the post WTO regime?

I_____

II_____

Appendix – 1.2

S.No	Name Of Company	Location
1	Alive Pharmaceuticals Pvt.	Biratnagar
2	Alliance Pharmaceuticals Pvt. Ltd	Simra, Birgunj
3	Apex Pharmaceuticals Pvt.Ltd	Parwanipur, Birgunj
4	Arya Pharmalab Pvt. Ltd.	Rampur, Kokani, Parwanipur, Birgunj
5	Asian Pharmaceuticals Pvt. Ltd	PPadsari, VDC-9 Rupendehi, Bhairahawa
6	Birat Pharma Lab Pvt. Ltd.	Biratnagar, Morang
7	Chemi Drug Industries Pvt Ltd.	Bijeshwori, Kathmandu
8	Concept Pharmaceuticals (N) Pvt. Ltd	Birgung
9	CTL Pharmaceutical Pvt. Ltd	Sallaghari,Bhaktapur
10	Curex Pharmaceuticals Pvt. Ltd.	Janagal, Benepa, Kavre
11	Danium Laboratories (P) Ltd.	Parwanipur, Birgunj
12	Deurali-Janata Pharmaceuticals Pvt. Ltd.	Dhapasi,Kathmandu
13	Everest Pharmaceuticals Pvt. Ltd	Kuleswor Aavas chhetra Kuleswore, Kathmandu
14	Florid Laboratories Pvt. Ltd.	Dhapakhel VDC, WNO 8, Lalitpur
15	G.D. Pharmaceuticals Pvt. Ltd.	Birgunj, Parsa
16	Lomus Pharmaceuticals Pvt. Ltd.	Gongapu, Ringroad, Kathmandu
17	Manoj Pharmaceuticals Works Pvt. Ltd.	Industrial Estate ,Dharan
18	National Health Care Pvt. Ltd.	Nitanpur, Chhatabibra, Bara
19	Nepal Pharmaceuticals Lab. Pvt. Ltd	Jeetpur, Birgunj, Parsa
20	Ominica Laboratoriies Pvt Ltd.	Chitapole VDC-1 Banshghari, Bhaktapur
21	Pharmaceutical Company of Nepal Pvt Ltd	Motisar, Bara
22	Pharmaco Industries Pvt.Ltd.	Chhetrapati, Dhalko, Kathmandu
23	Quest Pharmaceuticals Pvt. Ltd.	Chhatapipra, Bara
24	Shiv pharmaceuticals Laboratories Pvt. Ltd	Dharan
25	Simca Laboratories Pvt. Ltd.	Balkumari, Thimi, Bhaktapur
26	S.R.Drug Laboratories Pvt. Ltd	Satungal VDC, Kathmandu
27	Summy Pharmaceuticals Ltd	Nawalparasi
28	Time Pharmaceuticals Pvt. Ltd.	Mukundapur WNO 5
29	Unique Pharmaceuticals (P) Ltd.	Chhatapipra, Bara, Birgung.
30	Vijayadeep Pharmaceuticals P. Ltd.	Saibu VDC, W.NO 4, Lalitpur

Appendix – 1.3

S.No	List of Person	Contacted Address
1	Mr. Bharat B. Thapa	Secretary, Ministry of Industry, Commerce and Supplies
2	Mr. Lav Kumar Devkota	Secretary, Ministry of Health & Population
3	Mr. Prachanda Man Shrestha	Joint Secretary, Ministry of Industry, Commerce and Supplies
4	Mr. Tana Gautam	Director General, Department of Industry
5	Mr. Bhupendra Bahadur Thapa	Chief, Department of Drug Administration
6	Mr. Udhav Adhikari	Director, Department of Industry
7	Mr. Din Dayal Bhattarai	Chief, Royal Drug Research Laboratory
8	Mr. T.R. Shakya	Royal Drug Research Laboratory
9	Ms. Bhim Kumari Thapa	Ministry of Industry, Commerce and Supplies
10	Mr. Mahendra Bdr. Amatya	Managing Director, Nepal Pharmaceuticals Laboratory Pvt. Ltd
11	Mr. Mahesh Gorkhali	Vice-President, Association of Pharmaceutical Producers of Nepal
12	Mr. Umesh Lal Shrestha	Secretary General, Association of Pharmaceutical Producers of Nepal
13	Mr. Janak Bdr. Karki	General Manager, Industrial District Management Ltd.
14	Mr. Bharat Gyanwali	General Manager, National Productivity & Economic Development Centre
15	Mr. Manohar B. Shrestha	Project Officer, ILO Project on Productivity and competitiveness
16	Mr. Radha Raman Upadyaya	Senior Drug Administrator, DDA
17	Mr. Gajendra B. Bhuju	Senior Pharmacist, DDA
18	Dr, Sudha Sharma	President, Nepal Medical Association
19	Mr.Mukunda R. Bhandari	Senior Consultant

Appendix – 2.1

Number of the pharmaceutical companies by country of origin registered at DDA

Country	Number of Companies
1. India	168
2. Nepal	39
3. Korea	6
4. Bangladesh	5
5. Belgium	4
6. France	4
7. Germany	3
8. Switzerland	3
9. UK	3
10. China	2
11. Holland	2
12. Japan	2
13. Malta	2
14. Australia	1
15. Bulgaria	1
16. Italy	1
17. Malaysia	1
18. Mexico	1
19. Pakistan	1
20. Sweden	1
21. Taiwan	1
22. Thailand	1
23. USA	1

Source: DDA, Nepal

Appendix – 2.2

Top 15 Imported Products in FY 2001

S.No	Name of Drug	Dosage Form	Retail Value Rs in Million	% in Total
1	Vitamins	Tablet/capsule	164.7	5.2
		Liquid		
		Injection		
2	Cephalosporins	tablet/capsule	134.8	4.3
		Liquid		
		Injection		
3	Cough Preparations	Tablet	130.4	4.1
		Liquid		
4	Ciprofloxacin	Tablet	107.3	3.9
		Injection		
		eye/ear drops		
		eye ointment		
5	Amoxycillin	tablet/capsule	96.9	3.6
		Liquid		
		Injection		
6	Antacids	Tablet	88.1	3.2
		Liquid		
7	Ampicillin+ Cloxacillin	tablet/capsule	77.3	2.5
		Liquid		
		Injection		
8	Omeprazole	tablet/capsule	40.4	1.3
9	Enzymes	tablet/capsule	38.5	1.2
		Liquid		
10	Calcium Preparations	Tablet	37.5	1.2
		Liquid		
11	Diclofenac	Tablet	37.0	1.2
		Ointment		
		Injection		
		Eye drops		
12	Ranitidine	Tablet	32.6	1
13	Cold Preparations (for common cold)	Tablet	27.2	1
		Liquid		
14	Povidone Iodine	Gargle	31.1	1
		Liquid		
		Ointment		
		vaginal tablet		
		Scrub		

15	Cotrimoxazole	Tablet	29.4	0.9
		Liquid		
Total			1124.2	35.7
Source: DDA report published on July 2001				

Appendix – 2.3

Brands Available in Nepal by Therapeutic Groups

Therapeutic Groups	No. of Brands
Anti-Infectives	628
Respiratory	337
Vitamins/Minerals	238
Gastrointestinal	402
Pain/Analgesics	325
Dermatologicals	278
Gynaecologicals	147
Cardiac	182
Neuro/Cns	207
Anti-Parasitic	189
Ophthal/Otolog	153
Anti-Diabetics	49
Others	238
Source: Org – IMS Retail sales audit	

Appendix – 2.4

Potential Global Markets for Pharmaceutical Products

S.No	Country	Value 1999	Value 2000	Value 2001	Value 2002	Value 2003
		US$ '000	US$ '000	US$ '000	US$ '000	US$ '000
1	USA	1,36,49,302	1,48,55,223	1,87,53,075	2,48,73,682	3,17,39,251
2	BELGIUM	50,23,617	55,50,824	83,53,902	2,10,17,642	2,37,56,969
3	GERMANY	86,69,566	88,12,361	1,06,80,890	1,74,29,332	2,07,00,588
4	UNTD KINGDOM	68,05,709	73,48,150	91,78,444	1,10,85,622	1,36,92,876
5	FRANCE	77,48,740	79,72,342	92,72,590	1,07,81,146	1,31,16,249
6	ITALY	61,95,795	60,00,894	70,59,156	87,54,127	1,07,23,066
7	SWITZERLAND	5,050,540	5,274,851	68,56,428	82,65,563	9,718,621
8	SPAIN	3,509,089	3,613,288	4,406,979	5,724,399	7,293,567
9	NETHERLANDS	4,174,597	3,993,144	4,879,989	6,080,397	6,970,850
10	JAPAN	4,593,414	4,775,041	5,051,516	5,426,182	6,193,098
11	CANADA	3,237,642	3,802,543	4,321,668	4,870,011	6,137,261
12	AUSTRALIA	2,068,734	2,358,186	2,385,279	2,829,683	3,597,714
13	AUSTRIA	2,177,946	1,791,624	2,027,283	2,448,692	2,977,318
14	IRELAND	1,197,482	1,417,223	1,722,952	1,948,822	2,426,584
15	POLAND	1,504,109	1,597,698	1,891,932	2,099,246	2,421,100
16	RUSSIAN FED	917,470	1,325,414	1,866,977	1,627,074	2,369,860
17	TURKEY	1,159,314	1,344,314	1,345,328	1,717,183	2,302,121
18	SWEDEN	1,443,859	1,340,639	1,448,893	1,840,541	2,200,464
19	GREECE	1,193,283	1,133,150	1,160,571	859,286	2,181,805
20	MEXICO	1,236,028	1,409,843	1,617,758	1,859,882	2,173,837
21	BRAZIL	1,950,518	1,804,255	1,910,178	1,930,850	1,886,086
22	DENMARK	921,939	902,062	1,097,042	1,357,183	1,718,059
23	CHINA	820,761	952,890	1,217,528	1,434,108	1,705,632
24	PORTUGAL	1,002,361	922,965	1,079,833	1,303,285	1,649,001
25	CZECH REP	775,981	754,389	891,199	1,068,099	1,453,765
26	SAUDI ARABIA	908,912	883,065	967,150	1,002,451	1,389,217
27	KOREA REP.	726,199	825,385	1,002,434	1,182,911	1,362,075
28	FINLAND	712,737	685,867	792,071	967,839	1,253,309
29	HUNGARY	596,883	584,349	664,813	815,298	1,188,780
30	NORWAY	722,920	742,214	747,867	939,911	1,083,069
31	HONG KONG	980,145	934,281	882,494	825,658	860,511
32	SOUTH AFRICA		666,096	688,401	650,389	838,963
33	SINGAPORE	741,667	717,392	767,259	810,745	820,486
34	ISRAEL	588,462	600,548	656,930	713,115	784,266
35	ALGERIA	534,751	466,366	503,395	656,439	765,015
36	IRAN (ISLM.R)	392,516	386,640	484,632	447,150	653,024
37	THAILAND	469,977	481,807	526,376		641,931

38	INDIA	372,814	383,436	429,416	589,272	635,307
39	ROMANIA	283,761	307,271	401,613	532,735	625,077
40	SLOVAKIA	346,820	356,046	400,401	484,969	595,642
41	COLOMBIA	410,449	457,925	499,849	519,632	511,510
42	VENEZUELA	326,651	461,688	610,351	506,503	483,196
43	ARGENTINA	818,195	774,028	761,285	478,378	NA
44	MALAYSIA	325,043	341,473	402,893	443,637	474,792
45	NEW ZEALAND	390,074	353,888	345,011	373,855	464,176
46	UKRAINE	270,496	288,767	373,560	457,902	NA
47	VIET NAM	329,495	393,861	398,122	436,404	NA
48	PHILIPPINES	384,333	347,320	361,382	367,541	415,157
49	CROATIA	212,364	230,819	236,872	297,197	401,830
50	LEBANON	276,858	254,736	293,098	335,088	392,698
51	SLOVENIA	208,933	227,739	247,663	298,343	387,279
52	EGYPT	344,532	337,824	432,538	500,827	361,741
53	CHILE	270,357	277,822	319,588	290,117	314,926
54	ECUADOR	164,005	198,715	258,783	289,150	308,550
55	LITHUANIA	186,748	187,605	242,959	256,321	305,593
56	COSTA RICA	177,293	232,069	250,943	267,739	289,370
57	GUATEMALA	177,391	185,223	244,148	254,470	285,409
58	PAKISTAN	271,754	245,102	230,538	224,122	273,837
59	BULGARIA	121,476	130,039	189,871	202,170	262,837
60	LUXEMBOURG	155,865	146,563	155,962	183,075	246,046
61	MOROCCO	149,465	133,286	157,262	181,430	239,323
62	TUNISIA	171,763	165,057	195,240	214,046	234,288
63	LATVIA	143,081	138,456	149,158	187,757	232,354
64	INDONESIA	173,895	214,804	183,578	190,966	226,322
65	PERU	207,398	200,095	218,031	222,946	225,500
66	KAZAKSTAN	59,335	89,702	117,781		219,402
67	JORDAN	146,006	136,325	157,680	175,542	209,342
68	BELARUS	159,188	223,628	171,838	168,066	205,923
69	EL SALVADOR	98,455	153,270	148,214	162,566	183,234
70	NIGERIA	95,886	136,197	110,551	197,830	140,808
71	NICARAGUA	105,712	98,545	122,762	114,513	140,345
72	PANAMA	125,090	128,432	130,072	117,965	139,977
73	CYPRUS	95,501	89,522	99,440	118,068	139,439
74	ESTONIA	77,981	80,290	88,238	103,198	124,402
75	COTE DIVOIRE	113,731	94,847	0	100,571	123,452
76	SERBIA, MTNEG	84,668	74,636	83,419	122,252	NA
77	KENYA	91,119	77,658	96,630	104,193	117,376
78	SRI LANKA	72,202	NA	85,322	97,524	NA
79	OMAN	65,378	66,392	81,489	85,885	96,698

80	ICELAND	62,254	62,544	66,170	73,864	95,475
81	BANGLADESH	NA	NA	121,328	NA	85,287
82	SENEGAL	59,633	44,388	56,944	64,551	79,667
83	JAMAICA	69,501	82,271	80,521	78,787	NA
84	GEORGIA	43,239	35,887	40,639	NA	77,277
85	BOSNIA HERZG	NA	NA	NA	NA	76,984
86	CAMEROON	44,952	45,653	50,927	67,134	76,087
87	URUGUAY	134,914	123,177	129,811	91,181	76,007
88	UGANDA	73,630	34,162	49,395	48,173	74,878
89	SUDAN	32,586	55,601	63,891	73,232	NA
90	MACEDONIA,REP	40,593	46,726	45,166	55,531	68,716
91	TRINIDAD TBG	41,601	42,663	48,063	53,718	63,955
92	ETHIOPIA	40,563	28,094	40,911	43,830	62,865
93	QATAR	38,077	41,644	53,790	58,215	NA
94	N.CALEDONIA	36,772	40,076	37,014	45,137	54,539
95	TANZANIA,U.R	41,939	34,168	53,221	38,005	54,061
96	ZIMBABWE	40,026	NA	26,919	53,394	NA
97	MOLDOVA, REP	21,854	41,893	31,525	50,654	52,446
98	BAHRAIN	NA	42,253	39,491	50,147	51,868
99	FR.POLYNESIA	32,058	36,930	36,679	37,778	46,335
100	GHANA	54,329	42,648	45,387	44,783	NA
101	ALBANIA	31,035	17,115	23,740	28,770	44,382
102	BOLIVIA	30,953	31,716	40,467	41,299	42,859
103	PARAGUAY	45,486	56,813	59,026	42,181	NA
104	MAURITIUS	29,603	30,197	32,748	34,313	41,621
105	BENIN	23,020	20,356	31,414	39,438	NA
106	BARBADOS	35,736	33,357	35,655	36,828	39,035
107	ARMENIA	32,530	42,294	NA	24,066	38,190
108	KYRGYZSTAN	19,077	NA	NA	28,209	37,582
109	SYRIA A. R.	NA	55,268	NA	67,990	36,339
110	MADAGASCAR	17,719	21,382	28,289	27,030	35,064
111	GUINEA	18,321	23,256	15,712	34,153	NA
112	AZERBAIJAN	24,868	39,763	23,504	22,936	31,977
113	GABON	29,947	30,520	31,382	31,957	NA
114	BURKINA FASO	24,391	25,758	22,715	31,039	NA
115	BRUNEI DAR.	NA	NA	23,209	24,530	30,415
116	NAMIBIA	NA	38,459	39,815	28,857	29,226
117	MACAU	18,496	27,920	22,099	24,263	28,370
118	MALAWI	13,718	14,599	23,717	23,102	26,173
119	ARUBA	NA	NA	NA	NA	24,515
120	ZAMBIA	19,638	23,606	20,474	22,283	NA
121	TOGO	12,604	10,260	11,503	15,372	20,773

122	PAPUA N.GUIN	NA	11,877	20,504	17,507	18,907
123	FIJI	NA	11,380	12,709	12,932	17,167
124	SWAZILAND	NA	19,782	19,002	16,940	NA
125	ANDORRA	17,041	13,861	13,577	16,755	NA
126	NIGER	7,858	11,356	9,311	12,005	16,685
127	LESOTHO	NA	4,846	18,253	16,222	NA
128	ERITREA	NA	10,059	27,527	15,565	NA
129	CENT.AF.REP	6,045	3,157	5,759	6,064	13,526
130	RWANDA	6,751	NA	8,550	13,731	12,826
131	BURUNDI	8,529	10,058	12,195	10,440	NA
132	GUYANA	6,303	12,009	7,278	8,653	9,680
133	BELIZE	6,192	6,800	7,467	7,975	8,992
134	MONGOLIA	3,085	6,718	7,446	NA	8,730
135	HONDURAS	117,119	6,351	7,714	8,277	NA
136	GREENLAND	5,159	4,566	4,847	5,053	NA
137	GAMBIA	5,258	3,099	2,117	4,653	NA
138	GRENADA	3,440	3,727	11,329	4,097	4,519
139	MALDIVES	3,693	3,813	3,780	3,824	4,131
140	ST.LUCIA	4,155	4,312	3,754	3,706	4,015
141	SEYCHELLES	NA	NA	8,215	3,885	NA
142	SIERRA LEONE	NA	NA	NA	3,563	NA
143	S.VINCENT-GR	2,414	2,232	2,489	2,715	2,832
144	DOMINICA	1,649	1,818	1,708	2,330	1,697
145	SAMOA	NA	NA	801	1,010	1,209
146	WALLIS FUT.I	NA	NA	1,131	1,034	1,139
147	COOK ISLANDS	NA	NA	447	503	718
148	ANGUILLA	NA	NA	NA	396	396
149	SAO TOME PRN	68	47	80	89	278
150	MONTSERRAT	102	121	127	151	153
151	ANTIGUA BARB	5,455	NA	NA	NA	NA
152	BAHAMAS	17,160	24,453	31,232	NA	NA
153	BHUTAN	1,830			NA	NA
154	BOTSWANA		36,826	34,432	NA	NA
155	CAPE VERDE	3,430	4,038	3,714	NA	NA
156	COMOROS	723	806		NA	NA
157	CUBA	32,480	37,591	54,039	NA	NA
158	DOMINICAN RP	143,059	139,805	160,699	NA	NA
159	FAEROE ISLDS	11,730	NA	NA	NA	NA
160	KIRIBATI	358	NA	NA	NA	NA
161	KUWAIT	166,694	138,130	149,211	NA	NA
162	MALI	27,110	24,355	36,029	NA	NA
163	MALTA	49,609	49,980	49,136	NA	NA

164	MOZAMBIQUE	NA	NA	20,212	NA	NA
165	NEPAL	36,486	49,760	NA	NA	NA
166	S.AFR.CUS.UN	649,228	NA	NA	NA	NA
167	ST.KITTS NEV	1,683	1,980	2,017	NA	NA
168	SURINAME	6,836	7,335	6,600	NA	NA
169	TAJIKISTAN	NA	508	NA	NA	NA
170	TONGA	NA	587	NA	NA	NA
171	TURKMENISTAN	26,617	30,407	NA	NA	NA
172	UNTD ARAB EMIRATES	171,955	343,090	280,738	NA	NA
173	VANUATU	NA	2,067	NA	NA	NA

Source: www.intracen.org(International Trade Centre)

Note: Data above includes the product groups of Pharmaceuticals Excluding Medicaments(541) & Medicaments including Veterinary products(542)

Appendix – 4.1

List of Least Developed Countries

S.NO	Country	Region	GDP Percaptia (US$)
1	Afghanistan	South Central Asia	700 (2003)
2	Angola	Middle Africa	$1,900 (2004 estimates)
3	Bangladesh	South – Central Asia	1 900 (2003)
4	Benin	Western Africa	1 100 (2003)
5	Bhutan	South Central Asia	1,300 (2002)
6	Burkina Faso	Western Africa	1 100 (2003)
7	Burundi	Eastern Africa	600 (2003)
8	Cambodia	South East Asia	1 900 (2003)
9	Cape Verde	Western Africa	Purchasing Power Parity - $1,400 (2002)
10	Central African Republic	Middle Africa	1 100 (2003)
11	Chad	Middle Africa	1 200 (2003)
12	Comoros	Eastern Africa	700 (2002)
13	Democratic Republic of the Congo	Middle Africa	700 (2003)
14	Djibouti	Eastern Africa	1 300 (2002)
15	Equatorial Guinea	Middle Africa	2 700 (2002)
16	Eritrea	Eastern Africa	700 (2002)
17	Ethiopia	Eastern Africa	700 (2003)
18	Gambia	Western Africa	1 700 (2003)
19	Guinea	Western Africa	2 100 (2003)
20	Guinea-Bissau	Western Africa	purchasing power parity - $900 (2003)
21	Haiti	Carribean (South America)	purchasing power parity - $1,600 (2003)
22	Kiribati	Oceania-Micronesia	purchasing power parity - $800 (2001)
23	Lao People's Democratic Republic	South East Asia	1 700 (2003)
24	Lesotho	Southern Africa	3 000 (2003)
25	Liberia	Western Africa	1 000 (2003)
26	Madagascar	Eastern Africa	francGDP per capita: $800 (2003
27	Malawi	Eastern Africa	600 (2003)
28	Maldives	South-Central Asia	3900(2002)
29	Mali	Western Africa	900 (2003)

30	Mauritania	Western Africa	1 800 (2003)
31	Mozambique	Eastern Africa	1 200 (2003)
32	Myanmar	South - East Asia	1,800 (2003)
33	Nepal	South - Central Asia	1 400 (2003)
34	Niger	Western Africa	800 (2003)
35	Rwanda	Eastern Africa	$1 300 (2003.)
36	Samoa	Oceania-Polynesia(South of Pacific Ocean)	purchasing power parity - $5,600 (2002)
37	São Tomé and Principe	Middle Africa	purchasing power parity - $1,200 (2003)
38	Senegal	Western Africa	$1 600 (2003)
39	Sierra Leone	Western Africa	500 (2003)
40	Solomon Islands	Oceania-Melanesia(South of Pacific Ocean)	purchasing power parity - $1,700 (2001)
41	Somalia	Eastern Africa	500 (2003)
42	Sudan	Northern Africa	1 900 (2003)
43	Timor-Lesté	South East Asia	purchasing power parity - $500 (2001)
44	Togo	Western Africa	1 500 (2003)
45	Tuvalu	Oceania-Polynesia (South of Pacific Ocean)	purchasing power parity - $1,100 (2000)
46	Uganda	Eastern Africa	1 400 (2003)
47	United Republic of Tanzania	Eastern Africa	600 (2003)
48	Vanuatu	Oceania-Melanesia (South of Pacific Ocean)	purchasing power parity - $2,900 (2002)
49	Yemen	Western Asia	800 (2003)
50	Zambia	Eastern Africa	800 (2003)
Source: www.un.org			