

RESEARCH ON
**WTO AND PUBLIC HEALTH
POLICY PRIORITIES FOR NEPAL**

Conducted For

Ministry of Health and Population (MoHP)
Ramshah Path, Kathmandu

Conducted By

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Acronyms

ADA	Agreement on Anti-dumping
ALICO	American Life Insurance Company
APPPC	Asia Pacific Plant Protection Commission
ARI	Acute Respiratory Infections
ASCM	Agreement on Subsidies and Countervailing Measures
BoP	Balance of Payment
Codex	Codex Alimentarius Commission
DDA	Department of Drug Administration
DFTQC	Department of Food Technology and Quality Control
DOI	Department of Industry
EU	European Union
FAO	Food and Agriculture Organisation
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
FSW	Female Sex Workers
GMP	Good Manufacturing Practice
IDU	Injecting Drug Users
IPPC	International Plant Protection Convention
IPRs	Intellectual Property Rights
LDCs	Least Developed Countries
LIC Nepal	Life Insurance Company Nepal
MFN	Most Favoured Nation
MoHP	Ministry of Health and Population
NBSM	Nepal Bureau of Standards and Metrology
NCS	Nepal Council of Standards
NMC	Nepal Medical Council
NNC	Nepal Nursing Council
NPC	National Planning Commission
NTBs	Non-tariff Barriers

ODCs	Other Duties and Charges
OIE	World Organisation for Animal Health
PHCs	Primary Healthcare Centers
PIC	Prior Informed Consent
R&D	Research and Development
S&DT	Special and Differential Treatment
SAWTEE	South Asia Watch on Trade, Economics & Environment
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures
TBT	Agreement on Technical Barriers to Trade
TRIPS	Agreement on Trade Related Aspects of Intellectual Property Rights
TRQ	Tariff Rate Quota
UNAIDS	Joint United Nations Programme on HIV/AIDS
US	United States
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

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RESEARCH ON WTO AND PUBLIC HEALTH POLICY PRIORITIES FOR NEPAL

As a rules-based multilateral trading body, the World Trade Organisation (WTO) has the potential to impact on public health, mainly in developing and least developed countries. This research analyses various aspects of the WTO, particularly its agreements that concern with public health, with a view to identifying the policy issues and priorities for Nepal, which became a WTO Member in April 2004. The research confines its focus to five agreements of the WTO – General Agreement on Tariffs and Trade (GATT); General Agreement on Trade in Services (GATS); Agreement on the Application of Sanitary and Phytosanitary Measures (SPS); Agreement on Technical Barriers to Trade (TBT); and Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). These multilateral agreements have direct and indirect bearing on the public health situation of WTO Member countries, including Nepal. The research provides an introduction to these agreements and deals with their relationship with public health; Nepal’s commitments under these agreements; and their implications on public health. Then the research identifies the policy flexibilities available for Nepal under these agreements and the policy challenges that the country needs to address for protecting and promoting public health. The research has been divided into three sections. The research was done on the basis of literature review and information gathered by interviewing the key informants from different government ministries/departments and private organisations. A matrix of public health policy priorities in relation to five agreements of the WTO and a table indicating other important issues have also been included in the annex part of the report.

SECTION ONE

1.1 Origin of the WTO

Prior to the establishment of the World Trade Organisation (WTO), multilateral trade used to be governed by the General Agreement on Tariffs and Trade (GATT), which was initiated at the Bretton Woods Conference, New Hampshire, the United States (US), held after World War II.¹ The GATT’s objective was to promote and regulate the liberalisation of international trade through “rounds” of trade negotiations. From 1947 to 1994, the GATT provided the rules for world trade. The 8th Round of multilateral trade negotiations, held in Uruguay in 1986 (known as the Uruguay Round) and concluded in April 1994 by the signing of Marrakesh Agreement², transformed the GATT³ into a new permanent international trade organisation, the WTO.

¹ The other two global bodies that emerged from the Conference were the International Monetary Fund and the World Bank.

² It is a binding agreement signed at the Marrakesh Ministerial Conference in April 1994. The agreement set up the WTO and contains the results of the Uruguay Round of multilateral trade negotiations.

³ The WTO replaced the GATT but it still exists as the WTO’s umbrella treaty for trade in goods, updated as a result of the Uruguay Round of multilateral trade negotiations.

1.2 Scope and nature of the WTO

The WTO formally came into being in January 1995. Unlike the GATT, the WTO does not merely deal with trade in goods. The creation of the WTO has expanded trade rules into new areas such as intellectual property protection and trade in services. Its remit now expands from cross-border transactions to areas that impact crucially on domestic policies, including in the industry, agriculture, food security, services and public health sectors.

The WTO is now an institution with 150 Members⁴. It is a “rules-based⁵” and “member-driven⁶” organisation, which oversees a large number of agreements defining the “rules of trade” between its Members (WTO, 2004). The WTO is also a negotiating forum for Members to resolve their trade disputes, for which there is a Dispute Settlement Body. The WTO was born out of negotiations, and everything the WTO does is the result of negotiations.

The WTO’s top decision making body is the Ministerial Conference. Its Ministerial is held at least once in two years⁷. Next is the General Council and is attended by ambassadors and Geneva-based country delegates and the meetings are held several times a year at the WTO headquarters in Geneva, Switzerland. Delegates, who attend day to day meetings of the WTO, are government representatives of WTO Members as well as representatives of observer organisations. All the decisions in the WTO are made by consensus amongst Members (www.wto.org).

At the heart of the WTO system are agreements that are negotiated and signed by a majority of Members and approved in their own national parliaments. These agreements form the basic rules for international trade within the framework of the WTO. The WTO agreements are lengthy and complex because they are legal texts covering a wide range of activities. They deal with: agriculture, textiles and clothing, telecommunications, industrial standards and product safety, food sanitation regulations, intellectual property, and much more. But a number of simple, fundamental principles run throughout all of these documents. These principles are the foundation of the multilateral trading system (Understanding the WTO 2003).

1.3 Principles of the WTO

There are certain guiding principles that determine the functioning of the multilateral trade body. These principles are: the trading system should be “without discrimination”, “freer”, “predictable”, “more competitive” and “more beneficial for less developed countries”.

⁴ Nepal became the 147th Member of the WTO in April 2004.

⁵ The WTO is a system of rules dedicated to open, fair and undistorted competition. For example, the rules on non-discrimination — most favoured nation and national treatment.

⁶ Decisions are taken by consensus among all member governments.

⁷ Till date, there have been six Ministerial Conferences. The first was held in Singapore in 1996, the second in Geneva in 1998, the third in Seattle in 1999-2000, the fourth in Doha in 2001, the fifth in Cancun in 2003 and the sixth in Hong Kong in 2005.

1.3.1 Non-discriminatory

There are two important non-discriminatory principles within the WTO system – most favoured nation (MFN) and national treatment. According to the MFN principle, a country should not discriminate between its trading partners and give them equally “most favoured nation” or MFN status. For instance, If Nepal imposes a 1 percent tariff on imports of kiwi fruit from New Zealand, MFN treatment would demand that Nepal extend the same treatment to the imports of kiwi fruit from other WTO Members. The national treatment principle means that a country should not discriminate between its own and foreign products, services or nationals and give them national treatment (Understanding the WTO 2003). For instance, it is, in fact, a commitment by Nepal – as a WTO Member – to treat foreign products in the same manner as it would treat domestic products, provided that the foreign products are “like”⁸ its domestic products (See Box 1.1).

Box 1.1: Non-discriminatory principles of the WTO

MFN principle: This principle is contained in Article I of the GATT 1994. Despite what its name suggests, it does not mean a country or countries grant special favours to any particular country. It actually bars special favours of any sort and implies that a treatment given to one Member should be applicable in equal measure to all other Members. MFN principle forms the basis of nearly all WTO agreements. MFN principle is considered to be the very pillar of the multilateral trading system (Das 1999). In its broadest definition, it means that every time a Member opens up its market, it has to do the same for all other Members regardless of its economic status.

National treatment principle: This principle is mentioned in Article III of the GATT 1994. National treatment refers to non-discrimination between domestic products and imported products. The principle of national treatment prescribes the obligation that an imported product, after entering the country of import, should be treated as a national product (Das 1999). Though the principle of national treatment appears simple, its implementation has not been as simple due to emerging complexities that arise in international trade.

1.3.2 Freer trade

Another important aspect of the WTO system is encouraging freer trade through negotiations for the lowering of trade barriers. Lowering trade barriers is considered to be one of the most obvious means of encouraging trade between nations. The trade barriers constitute of custom duties (or tariffs) and measures, such as import bans or quotas that restrict quantities selectively (Understanding the WTO 2003).

1.3.3 Predictable

The predictability is ensured through the binding of tariff rates and market opening commitments, and through the transparency by disclosing the policies and practices publicly within the country or by notifying the WTO. This demands that foreign companies, investors

⁸ Like products are defined as similar products in a market that can act as substitute products for the ones being imported.

and governments be confident that trade barriers (including tariffs and non-tariff barriers) are not raised arbitrarily; and tariff rates and market-opening commitments are “bound” in the WTO. In addition, many WTO agreements require governments to disclose their policies and practices publicly within the country or by notifying the WTO. The regular surveillance of national trade policies through the Trade Policy Review Mechanism provides a further means of encouraging transparency both domestically and at the multilateral level (Understanding the WTO 2003).

1.3.4 More competitive

The WTO is a system of rules dedicated to open, fair and undistorted competition. The rules on non-discrimination — MFN and national treatment — are designed to secure fair conditions of trade. So too are those on dumping (exporting at below cost to gain market share) and subsidies. The issues are complex, and the rules try to establish what is fair or unfair, and how governments can respond, in particular by charging additional import duties calculated to compensate for damage caused by unfair trade. Many of the other WTO agreements aim to support fair competition: in agriculture, intellectual property, services, for example. (Understanding the WTO 2003).

1.3.5 More beneficial for less developed countries

The WTO system is considered to be more beneficial for less developed countries since it gives them more time to adjust, greater flexibility, and special privileges. Developing countries need flexibility in the time they take to implement the system’s agreements. And the agreements themselves inherit the earlier provisions of the GATT that allow for special assistance and trade concessions for developing countries. Besides, the agreements have given them transition periods to adjust to the more unfamiliar and difficult WTO provisions — particularly, so for, the poorest, least developed countries (LDCs). A ministerial decision adopted at the end of the Uruguay Round says better-off countries should accelerate implementing market access commitments on goods exported by the LDCs, and it seeks increased technical assistance for them. More recently, developed countries have started to allow duty-free and quota-free imports for almost all products from the LDCs (Understanding the WTO 2003).

1.4 Interrelation between the WTO and public health

Experts have defined public health as “the effort to protect, promote, and restore the people’s health; the combination of sciences, skills, and beliefs directed to the maintenance and improvement of the health of all the people through collective or social actions; and a social institution, a discipline, and a practice with the goal to reduce the amount of disease, premature death, and disease-produced discomfort and disability in the population.” In the context of the globalised world, these different dimensions of public health are at stake. For instance, if we perceive the recent trend of international trade under the WTO system, we notice that the rules and the agreements of the WTO have transformed the capacity of governments to monitor and protect public health; regulate occupational and environmental health conditions and food products; and ensure affordable access to medications.

WTO rules and agreements can directly or indirectly affect public health in a number of ways. Although the agreements imply the same rules for all Members, their impact can be diverse and different depending on the level of domestic economic prosperity and priorities of Members. Though priorities and policies might differ amongst Members, it is evident that health is becoming a crucial issue due to the impact international trade can have on the cost of medication, technology transfer to developing countries and the LDCs, improvement of medical infrastructure, movement of people, products, diseases etc. The interrelationship between trade, economic prosperity and health is apparent. If economic welfare can increase standards of living, it can also increase access to medications, health facilities and public health related products. Reducing tariffs may lead to lower prices for medical equipment and health related products; changing international rules concerning patent protection may affect the prices of medicines and vaccines; importantly also, there is a positive link between freer trade and economic growth, which can lead to reduced poverty and higher standards of living, including health (WTO/WHO 2002). Therefore, it is important to examine the growing relationship between public health and international trade. One must note that reforms to global economic governance are vital in the interests of health. All bilateral, regional and multilateral trade agreements should be subject to health and equity impact assessments (GHW 2005).

A joint report of the World Health Organisation (WHO) and the WTO, published in 2002, identifies several public health issues that relate with multilateral trading system, espoused by the WTO. Major issues identified in the report are infectious disease control, food safety, tobacco control, environment protection, access to medication, health services, food security, and nutrition.

1.4.1 Infectious disease control

The world today has witnessed the emergence of new global health threats, for which control measures are still evolving (for example HIV/AIDS, Ebola and Marburg viruses) (WTO/WHO, 2002). For developing countries and the LDCs, even older diseases like tuberculosis, malaria, etc., pose threats and as these diseases become immune to traditional drugs, the cost and availability of new age drugs pose a challenge for developing countries and the LDCs. These diseases can incur an economic burden on countries, particularly those which are under prepared or unprepared to tackle them. Most developing countries and the LDCs still face problems with traditional disease outbreaks but developed countries are also facing increasing risks with new diseases like SARS. With growing international trade as well as travel, these outbreaks are beginning to have severe economic impacts. The economic cost of infectious disease outbreaks is increasingly becoming a global concern. Estimates on the cost of the SARS outbreak range from US\$ 10 billion to US\$ 30 billion (www.aph.gov.au).

1.4.2 Food safety

Several new sources of food-borne diseases are of increasing relevance to international trade, for instance, dioxin residues in animal feed or the spread of mad cow disease and its probable onward transmission to people (WTO/WHO 2002). Growing consumer awareness increases the use of standards and safeguards for food safety. In this regard, the WTO has agreements like the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS). It provides governments the right to restrict trade for health reasons but the measures taken up to restrict trade must be based on scientific evidence. The agreement recognises food safety standards and

guidelines established by the Food and Agriculture Organisation (FAO)/WHO Codex Alimentarius Commission (Codex).

1.4.3 Environment

The link between the environment, health and trade is complicated and not easily interpreted. Removing trade barriers to modern “green” technologies and to suppliers of environmental goods and services can potentially benefit both the environment and health (WTO/WHO 2002). However, trade in dangerous and hazardous chemicals can increase environmental as well as health risks. Mismanaged trade and environmental policies can have an adverse impact on a vulnerable environment and subsequently on public health. Many WTO agreements are relevant to environmental issues. Multilateral environment agreements represent an important multilateral course of action to address specific environmental issues, which may also be relevant to health, such as, for example, limiting the use of ozone-depleting substances (WTO/WHO 2002). Therefore, such a tripartite relationship between the environment, health and trade is of utmost importance and concern for developing countries and the LDCs.

1.4.4 Access to drugs and vaccines

One third of the world’s population lacks access to essential drugs and over 50 percent of people in poor countries in Africa and Asia do not have access to even the most basic essential drugs. There are different levels at which access can be determined. The import and consumption of essential drugs and vaccines is one aspect of access while other aspects include the provisions of health posts and facilities, adequately dispersed information, physical infrastructure to reach remote areas, etc. Access to essential medicines and vaccines depends on various critical elements: rational selection and use, sustainable financing, reliable and affordable prices (WTO/WHO 2002). The cost of medication is likely to be influenced by WTO agreements like the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

1.4.5 Health services

The General Agreement on Trade in Services (GATS) of the WTO covers the movement of health professionals and services. GATS leaves countries the flexibility to manage trade in services in ways that are consistent with their national health policy objectives. The movement of health professionals and services has an impact on public health. As more and more countries look to attract health consumers and health related investment, international trade is able to enhance the quality and efficiency of health related supplies. In few developing countries such as Thailand and Jordan, the health sector serves as a regional supply centre that attracts foreign patients, who can contribute to domestic income and employment (WTO/WHO 2002). However, there are also challenges associated with liberalisation of trade in services such as it might lead to the shortage of health professionals in the home country.

1.5 Focus of the research

In the backdrop of issues concerning international trade and implications on public health, this research deals with the following five agreements of the WTO.

- General Agreement on Tariffs and Trade (GATT)
- General Agreement on Trade in Services (GATS)
- Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)
- Agreement on Technical Barriers to Trade (TBT)
- Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)

These agreements have many direct and indirect bearings on the public health situation of WTO Members, including Nepal. It is, therefore, important to understand their nature and provisions so that the government could develop national strategies to protect and promote public health in the post WTO accession era.

1.6 Objectives of the research

The objectives of the research are to:

- Enable the government authorities to utilise the policy flexibilities available under the above mentioned five agreements of the WTO and protect and promote public health in the post WTO accession era;
- Provide recommendations on the WTO and public health policy priorities to the trade negotiators so that they could take a proactive stance at the multilateral level; and
- Disseminate the research report findings to sensitise and make aware the stakeholders (such as consumers, pharmaceutical entrepreneurs and medicinal practitioners) of the implications of the WTO on public health in Nepal.

1.7 Methodology of the research

- The study was done on the basis of literature review and interviews with key informants (see Annex 3 for information about them).
- A discussion forum titled Promotion of Nepalese Pharmaceutical Companies in the WTO Era, which was organised by SAWTEE on 17 December 2005 in Kathmandu, helped the researchers to update the report.

1.7 Limitations of the research

- Due to limited resources and time, the research has not gone into the details of each and every issue identified under the report. There is a scope of further research on such issues such as in the case of trade remedy measures and compulsory licensing and parallel import – TRIPS flexibilities (see Annex 2 for other issues). For example, another research study focussing on the National Health Policy of Nepal and Provisions of the WTO Agreements affecting them can be done.
- WTO and public health issues are new to most Nepalese stakeholders, including the government officials and there has not been enough research on WTO related issues. This limited the scope of gathering Nepal specific cases/evidences while dealing with WTO agreements.
- The data from the secondary sources might not be accurate and valid in all cases.

SECTION TWO

2.1 WTO agreements and public health

2.1.1 General Agreement on Tariffs and Trade

The Agreement Establishing the World Trade Organisation calls for a single institutional framework encompassing the GATT (WTO 2005). Since GATT forms the institutional and legal framework for the WTO, its framework covers most WTO agreements that are related to public health such as SPS, TBT and TRIPS. GATT deals with various aspects of multilateral trade such as:

2.1.1.1 Tariff

The agreement requires Members to bind their tariffs on all products, including health related products. The main disciplines on tariffs are contained in Articles II and XXVIII of the GATT 1994. The former prescribes the limits on the imposition of tariffs and the latter contains the procedure for raising tariffs beyond specified levels (Das 1999). Members cannot raise their tariffs beyond the bound rates in practice except on particular circumstances. Within the GATT, there is also a provision for maintaining tariff rate quota (TRQ)⁹ and preferential tariff rate¹⁰.

2.1.1.2 Non-discriminatory principles

Although the GATT, as an institutional and legal framework, covers most aspects of WTO agreements, it is more clearly evident in its two most basic principles – MFN and national treatment (See sub-section 1.3.1 for details). Although the principle of MFN requires all Members to be treated equally, its exception in public health related cases is unique and provides safeguards as well as potential complications in its interpretation during trade disputes.

2.1.1.3 Exceptions

Health exceptions are provided in GATT Article XX. It allows Members to restrict imports or exports from/to specific sources. Such measures can be taken for some specified purposes, for instance, for the protection of public morals, protection of human, animal or plant life or health (Das 1999). For example, health authorities of Nepal may decide to restrict the import of Mango from any Member country on grounds of health risk, like high level of pesticides in Mango. In doing so, it will affect trade in that particular product but this is a legitimate move if it's based

⁹ The tariff quota is the quantity of import up to which a lower level of tariff is applied; beyond that limit of quantity, the normal tariff in the schedule is applied.

¹⁰ The general tariff listed in the tariff schedule is to be applied to all Members without discrimination. Besides, Members sometimes apply concessional rates of tariff to some products of some specified Members. These are preferential tariffs and are recorded in the tariff schedule, specifically mentioning the names of the Members for whom they are applicable.

on scientific evidence and becomes a justifiable trade barrier under WTO rules. This provision of the GATT also incorporates other WTO agreements like TBT and SPS into its fold.

2.1.1.4 Trade remedy measures

There are four different trade remedy measures that are dealt by the GATT (and further guided by separate agreements on them). The GATT provisions for these measures with certain conditions that Members need to fulfill while applying them at the domestic level. The measures are: safeguard measures; anti-dumping measures; countervailing measures and balance of payment measures¹¹ (See Box 2.1).

Box 2.1: Trade remedy measures as options to protect domestic companies

Safeguard measures: These measures are emergency trade measures taken temporarily by a Member to provide relief to its domestic industry in the situation of injury from an increase in imports. A Member may take recourse to trade measures restricting its imports of a product so as to “safeguard” its domestic industry. A separate agreement, Agreement on Safeguards, has also been incorporated within the WTO for a detailed application of safeguard measures. Taking safeguard measures means withdrawing or modifying the concessions which a Member has given under the WTO agreements in respect of goods; or suspending, wholly or partly, other obligations undertaken in the WTO agreements in respect of goods. Examples of the former are: withdrawal of concession by raising the tariff on a product above the bound level; or modification of the concession by raising the tariff level for imports beyond a particular value or volume. An example of the latter may be the imposition of quantitative restrictions to limit the import of a product in suspension of the obligation not to restrict import (Das 1999).

Anti-dumping measures: The rule governing anti-dumping are dealt with by the Agreement on Anti-dumping (ADA, but officially known as Agreement on Implementation of Article VI of the GATT 1994). If a foreign supplier sells goods at a price below his/her cost of supplying the same goods in the domestic market, it is considered an act of dumping. Governments can take anti-dumping measures against such action, for instance, by levying an amount equivalent to the margin of dumping at the border. However, the remedial process requires the determination of three elements: existence of dumping; existence of injury; and causal relation between dumping and injury (Adhikari 2004).

Countervailing measures: While anti-dumping measures are taken to create a level playing field for the domestic enterprises to protect them against unfair competition by the foreign enterprises, countervailing measures are taken for the same purpose except that these measures are taken to counteract the action taken by the foreign governments (providing subsidies). Agreement on Subsidies and Countervailing Measures (ASCM) governs countervailing measures. When a foreign government provides trade distorting subsidies to its domestic enterprises, the home country has a right to impose additional duty over and above the normal duty in order to countervail the impact of such subsidy in the home market (Adhikari 2004).

¹¹ While dealing with public health policy priorities and options to protect domestic pharmaceutical companies, the BoP measures are not that much important.

2.1.2 General Agreement on Trade in Services

As a result of the Uruguay Round negotiations, GATS entered into force within the WTO system in 1995. The agreement creates the multilateral legal framework for international trade in nearly every type of service. The agreement's 29 articles establish the scope of its rules' coverage, impose general obligations, structure the making of specific commitments, construct a process for progressive liberalisation of trade in services, and link the treaty to the WTO's Dispute Settlement Mechanism (WHO 2004). GATS recognises four modes of services supply (See Box 2.2).

Box 2.2: Modes of services supply under GATS

- | | |
|---------------|--|
| Mode 1 | Cross border supply: A consumer of a particular country receives service from a service supplier of another country without being physically present through various means of communication (for example, telemedicine, medical transcription or international health insurance policies). |
| Mode 2 | Consumption abroad: A consumer travelling to another country for the consumption of services such as health, education, etc. (for example, patients going to another country for medical checkup). |
| Mode 3 | Commercial presence: A foreign company setting up operations within another country to deliver services. It deals mainly with foreign direct investment (FDI) and technology transfer in the services sector (for example, legal establishment of a foreign service supplier in a country). |
| Mode 4 | Temporary movement of natural persons: Movement of people (professionals) to another country to provide services on a temporary basis (for example, individuals such as doctors and nurses traveling to another country to supply service there on a temporary basis). |

GATS consists of:

- (i) general rules or obligations applicable to all service sectors – based on the principle of transparency and the MFN treatment; and
- (ii) specific commitments listed in a country's schedule – in which each Member specifies the level of market access and the degree of national treatment it is prepared to guarantee to the foreign service suppliers.

As per Article II of GATS, WTO Members must accord immediately and unconditionally to services and service suppliers of any other Member treatment no less favourable than that it accords to like services and service suppliers of any other Member. With respect to market access through the modes of supply, Members must accord services and service suppliers of any other WTO Member treatment no less favourable than that provided under the terms, limitations and conditions agreed and specified in its schedule of specific commitments. Likewise, in national treatment, each Member must accord to services and service suppliers of any other WTO Member, in respect of all measures affecting the supply of services and any conditions and qualifications set out therein, treatment no less favourable than that it accords to its domestic service and service suppliers.

The WTO has classified services into 12 sectors and further into 155 sub-sectors. WTO Members have, in their discretion, choice to liberalise the sectors and sub-sectors and list them in their schedule of specific commitments (in which they assume obligation under the four modes of supply). Market access and national treatment commitments are specified for each Mode within each scheduled sector. There are three principal options:

- (i) Full commitment, that is commitment without limitation;
- (ii) Limited (or partial) commitment, which is subject to some restrictions or qualifications; and
- (iii) No commitment (“unbound”), where the Member remains free to introduce restriction on trade in the mode at any time.

Box 2.3: GATS and public health related sectors

With respect to public health, out of 12 sectors classified by the WTO under GATS, business services, education services, distribution services, financial services, environmental services, and health related and social services are the sectors that have direct or indirect implications on public health.

- **Business services** include professional services such as medical and dental services, services provided by midwives, nurses, physiotherapists and para-medical personnel. Business services also include the movement of these health professionals.
- **Education services** include training, education (higher studies) and investment in medical studies.
- **Distribution services** primarily include the distribution of pharmaceuticals and medical equipments through commission agents, wholesale trader, retailer, etc.
- **Financial services** include accident and health insurance.
- **Environment services** include sewage services, refuse disposal services, sanitation and similar services, cleaning of exhaust gases, noise abatement services, and nature and landscape protection services.
- **Health related and social services** include hospital services and other human health services. Services delivered under the direction of medical doctors chiefly to in-patients aimed at curing, reactivating and/or maintaining the health status fall under the hospital services while ambulance services, residential health facilities services other than hospital services; social services with or without accommodation fall under other human health services. However, health related and social services do not include medical and dental services, and the services provided by nurses, midwives etc. These services are professional services and fall under business services.

It should be noted that the absence of a commitment does not mean that trade is prohibited; trade may occur, depending on the already existing rules and regulations, but foreign suppliers have no guarantee of market access or national treatment. Moreover, limitations may be attached to commitments in order to reserve the right to initiate measures inconsistent with full market access and/or national treatment. However, liberalisation of basic amenities provided to the public in the exercise of governmental authority (“provided neither on a commercial basis nor in competition with one or more service suppliers”) is exempted from GATS.

2.1.3 Agreement on the Application of Sanitary and Phytosanitary Measures

Discovery of new diseases such as SARS, Bird flu, etc., and threat to human, animal and plant life and health have become a growing concern the world over. Ensuring safety of food for human consumption and prevention of the spread of pest and disease among animals and plants is a sovereign right of every country. Countries have different regulations to safeguard the life and health of its people, animals and wild flora – The Food and Drug Administration (FDA) Regulations in the US and The Food and Feed Regulations in the European Union (EU) are some examples. However, such regulations can be used as an excuse for protecting domestic producers as trade barriers to restrict imports from other countries. To enforce preventive measures necessary to protect human, animal and plant life or health and at the same time to make sure such measures are not applied arbitrarily as a disguised restriction on international trade, the WTO has an agreement, called the SPS Agreement.

Box 2.4: Purpose of SPS measures

SPS measures have been included within the WTO with the following purposes:

- (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
- (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
- (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests;
or
- (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

SPS measures can take many forms, such as requiring products to come from a disease-free area, inspection of products, specific treatment or processing of products, setting of allowable maximum levels of pesticide residues or permitted use of only certain additives in food. Sanitary (human and animal health) and phytosanitary (plant health) measures apply to domestically produced food or local animal and plant diseases, as well as to products coming from other countries (www.wto.org).

SPS measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment etc. (Pandey 2004).

The agreement confers rights to apply SPS measures to the extent necessary to protect human, animal or plant life or health based on the scientific principle supported by sufficient scientific evidence. However, when existing scientific evidence is insufficient to determine risk, Members

can provisionally adopt SPS measures on the basis of available pertinent information, including that from the relevant international organisations as well as from SPS measures applied by other Members. Besides, while applying SPS measures, the non-discriminatory principles – MFN and national treatment – should also be taken into account.

In order to harmonise SPS measures, Members have been encouraged to use international standards, guidelines and recommendations where they exist. They are encouraged to participate in a number of international standard setting organisations such as Codex, the International Office of Epizootics (for animals), and the relevant international and regional organisations operating within the framework of International Plant Protection Convention (IPPC). However, Members may use measures, which result in higher standards if there is scientific justification. They are also allowed to set higher standards based on appropriate assessment of risks so long as the approach is consistent, not arbitrary.

The SPS agreement attempts to clarify rules on risk assessment. Risk assessment is described as: the evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the SPS measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

2.1.4 Agreement on Technical Barriers to Trade

Governments lay down mandatory technical regulations on products for reasons of security, health or environment. In doing so, these regulations can vary from country to country. Having too many standards that vary between countries can be complicated, thus creating barriers to trade and making it more difficult for producers and exporters. In order to maintain uniformity in technical regulations, it was imperative to develop standards that were widely accepted. Widely accepted standards make it possible to have uniform designs, machinery, tools and inputs, resulting in economy of production and an assurance of quality (Das 1999). For such uniformity to be maintained, the TBT agreement encourages Members to adopt international standards. The agreement recognises individual country's rights to adopt domestic standards, which they consider appropriate in order to safeguard human, animal, plant life or to protect the environment.

Government regulations or industry standards for goods can impact trade in, at least, several ways: They can facilitate exchange by clearly defining product characteristics and improving compatibility and usability; they also advance domestic social goals like public health by establishing minimum standards or prescribing safety requirements (www.cid.harvard.edu). Agreements like TBT seek to maintain a dual approach. One is to give Members the right to adopt domestic standards, which they consider appropriate according to their domestic requirements. The other is to encourage the use of international standards so that trade disputes and diversity (variation in applicable standards) are minimised.

All Members have the right to restrict trade for “legitimate objectives” under TBT. These “legitimate objectives” include the protection of human health or safety, the protection of animal or plant life or health, protection of the environment, national security interests and the

prevention of deceptive practices. The Agreement applies to product requirements that are mandatory (technical regulations) as well as voluntary (standards). It covers such requirements developed by governments or private entities whether at the national or regional level. Whenever there is a lack of a precise definition to terms like “obstruction” or “unnecessary”, the interpretation of these terms can be done by taking the matter to the WTO’s Dispute Settlement Body.

The Agreement states that the technical regulations, standards and procedures for conformity assessment are to be applied to products imported from other Member countries based on the principles of non-discrimination. It means that no less favourable treatment should be accorded to like products of national origin and to like products originating in any other country. The TBT agreement states that if international standards exist for a specific field, then Members are advised to use these standards for their own domestic technical regulations that are imposed on imports.

The agreement has recognised the problems that countries like Nepal face while complying with its provisions. It has, therefore, urged Members to take into account the special development, financial and trade needs of developing country Members and provide special and differential treatment (S&DT) to such Members. For example, the agreement requests Members to provide technical assistance to such Members in any or all areas covered by the provisions of the agreement.

2.1.5 Agreement on Trade Related Aspects of Intellectual Property Rights

The inclusion of TRIPS within the WTO has expanded the scope of world trade from trade in goods and services to intellectual property rights (IPRs). Establishing a minimum standard of IPRs is the main aim of the agreement. Members have to provide a minimum standard of protection for all intellectual property applied to all technologies in products and processes.

Intellectual property refers to the creation of the mind in the form of ideas and knowledge. IPR is the right granted to a person for his/her intellectual creation where he/she uses his/her ideas and knowledge. While granting an IPR to a person, the right is conferred exclusively for a definite period (in some types of IPRs for an indefinite period) to the creator.

The main purpose of granting IPRs is to legally recognise, reward and encourage the creator for his/her intellectual creation. IPRs are also granted with the principle that such recognition, reward and encouragement lead to the protection and development of ideas and knowledge. IPRs under TRIPS include copyright, trademark, geographical indications, patent, industrial design, trade secret, and layout design of integrated circuit. These IPRs have been divided into two parts – copyright and related rights and industrial property rights.

2.1.5.1 Copyright and related rights

Copyright includes the right relating to literary and artistic works (book, article, music, painting, movie etc.). Such a right is granted for a minimum period of 50 years after the death of the copyright holder. Likewise, under copyright, rights of performers (actor, singer, musician etc.), producers of phonograms (sound recordings) and broadcasting institutions are also

protected. The main purpose of granting such rights is to encourage and reward the creative literary and artistic works and the creators of such works.

2.1.5.2 Industrial property rights

Industrial property rights can be divided into two categories. In the first category, distinctive signs – especially trademark, which distinguishes a particular good or service from another good or service and geographical indication, which distinguishes a particular good from another good on the basis of geography (for instance tea of Ilam) – are protected. The protection to these IPRs can be given for an indefinite period provided the signs used continue to remain distinctive. The protection of such distinctive signs is meant to stimulate and ensure fair competition and to protect consumers, by enabling them to make informed choices between various goods and services. In the second category is patent, which is granted for innovations (medicine); industrial design, which is granted for new designs of goods; and trade secrets, which are granted for maintaining secrecy on matters relating to trade (production related information or marketing information). While patent can be protected for 20 years and industrial design for at least 10 years, trade secrets can be protected till the period the right holder wants. The social purpose is to provide protection for stimulating investment in the development of new technology, thus providing incentive and means to finance research and development activities.

Besides these, there are other IPRs that are dealt by TRIPS – layout designs of integrated circuit, which is granted in the field of electronics (digital programme) and plant breeders' right, which is given for the protection of plant varieties (new variety of a plant).

Notwithstanding the acrimonious debates on whether or not to include TRIPS within the WTO framework, the agreement came into force along with the establishment of the multilateral trading body. However, given the continued resistance from the developing and least developed countries, Members were required to implement the agreement keeping in consideration their “development status”. While developed countries were given a period of one year (1 January 1996) to implement the agreement and developing countries were given a period of five years (1 January 2000), the LDCs were provided with an 11 year transition period to implement the agreement (1 January 2006). In the case of the LDCs, the transition period has been recently extended, i.e., until 2013¹².

TRIPS requires Member governments to harmonise their national IPR system with global rules and provide patent protection for any invention – whether it is a product (such as a medicine) or a process (such as a method of producing the chemical ingredients for a medicine) – for at least 20 years. Under TRIPS, three criteria to qualify for a patent have been set:

- an invention has to be new (novelty);
- it must be an inventive step (non-obviousness); and
- it must have industrial applicability (useful).

¹² The decision was recently made in December 2005.

The governments can, however, refuse to grant patents for three reasons (See Box 2.5).

Box 2.5: Governments' flexibility to refuse to grant patents

- inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life or health. *Article 27.2*
- diagnostic, therapeutic and surgical methods for treating humans or animals. *Article 27.3a*
- certain plant and animal inventions. *Article 27.3b*

Source: www.wto.org

The patent rules within TRIPS have, however, generated much controversy in recent years. The North-South divergence is apparent – particularly in relation to access to medicines – during WTO negotiations and the debate continues on how to balance the interests of both. The Southern countries perceive that the patent rules are set to further restrict poor people's access to vital life-saving drugs by allowing companies to create a monopoly and charge high prices. The Northern countries argue that the strengthening of IPRs is essential for encouraging companies to invest more in research and development and find solutions to global health problems by producing new or more effective drugs.

2.2 The Doha declaration and recent developments

Internationally, the concept of “Health for All” has been an important factor in ensuring that medicines are cheap and affordable. In 2001, WHO-supported Commission on Macroeconomics and Health strongly demanded for large-scale financial commitment by rich countries to scaling up the access of the world's poor to essential health services. There have been some important initiatives in this direction, however, only half-heartedly. For example, multilateral institutions and programmes, such as UNAIDS, the Global Fund to Fight AIDS, Tuberculosis and Malaria and the WHO ‘3 by 5’ strategy to deliver antiretroviral therapy to 3 million people by 2005, remain under-funded (NPC and UNDP 2005).

In the case of TRIPS and public health, some initiatives have been taken at the WTO. During the fourth Ministerial of the WTO held in Doha in November 2001, WTO Members made a historic move. In the main Doha Declaration of 14 November 2001, Member governments stressed that it is important to implement and interpret TRIPS in a way that supports public health, by promoting both access to existing medicines and the creation of new medicines. In addition, they also adopted a separate Declaration on TRIPS and Public Health. In this Declaration, they agreed that TRIPS does not and should not prevent Members from taking measures to protect public health. They underscored countries' ability to use the flexibilities that are built into TRIPS, including “compulsory licensing¹³” and “parallel importing¹⁴”. They also agreed to

¹³ Compulsory license is used when the judicial or administrative authority is allowed by law to grant a license, without permission from the holder, on various grounds of general interest (for example, absence of working, public health, economic development, and national defence).

¹⁴ Products imported into a country without the authorisation of the right holder in that country, which have been put on the market in another country by that person or with his consent. According to the theory of exhaustion of IPRs, the exclusive right of the patent holder to import the protected product is exhausted, and thus ends, when

extend exemptions on pharmaceutical patent protection for LDCs until 2016. On one remaining question, they assigned further work to the TRIPS Council to sort out how to provide extra flexibility, so that countries unable to produce pharmaceuticals domestically can obtain supplies of copies of patented drugs from other countries (This is called the “Paragraph 6” issue as it comes under that paragraph in the separate Declaration on TRIPS and Public Health) (www.wto.org).

According to Article 31(f) of TRIPS, products made under compulsory licensing must be “predominantly for the supply of the domestic market”. This applies to countries that can manufacture drugs. It limits the amount they can export when the drug is made under compulsory license. And it has an impact on countries unable to make medicines and therefore wanting to import generic drugs. They would find it difficult to find countries that can supply them with drugs made under compulsory licensing.

This problem was resolved on 30 August 2003 through a “Decision on the Implementation of Paragraph 6”. WTO Members agreed on legal changes to make it easier for countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines themselves. The decision waives exporting countries’ obligations under Article 31(f) – any Member can export generic pharmaceutical products made under compulsory licences to meet the needs of importing countries, provided certain conditions are met. The waiver was interim, and the ultimate goal was to amend TRIPS within the first half of 2004. However, Members could not do that by that time. There has been some progress recently (See Box 2.6).

Box 2.6: WTO decision on patent and public health

WTO members on 6 December 2005 approved changes to the intellectual property agreement making permanent a decision on patents and public health originally adopted in 2003. The decision directly transforms the 30 August 2003 “waiver” into a permanent amendment of TRIPS. That waiver made it easier for poorer countries to obtain cheaper generic versions of patented medicines by setting aside a provision of TRIPS that could hinder exports of pharmaceuticals manufactured under compulsory licences to countries that are unable to produce them. This decision will now be formally built into TRIPS when two thirds of the WTO’s Members have ratified the change. They have set themselves until 1 December 2007 to do this. The waiver remains in force until then.

Source: www.wto.org

Following the continued debate on this issue in the past, LDC Trade Ministers’ Meeting in June 2005 through the Livingstone Declaration had demanded that there was a need to urgently amend TRIPS to incorporate the “30 August 2003 Decision on the Implementation of Paragraph 6 of the Declaration of TRIPS and Public Health” as a permanent solution to the LDC problems with insufficient or no manufacturing capacity (Livingstone Declaration of the LDCs 2005). Nepal had also officially participated in the Meeting and adopted this Declaration.

the product is first launched on the market. When a State or group of States applies this principle of exhaustion of IPRs within a given territory, parallel importation is authorised to all residents in the State in question. In a State that does not recognise this principle, however, only the patent holder that has been registered has the right to import the protected product.

SECTION THREE

3.1 Public health and Nepal

3.1.1 Public health status

The health status of most Nepalese is often cited as being poor. It is claimed that many Nepalese, especially in the rural areas, live without basic health services and facilities. However, some improvements have been observed since early 1990s. Provision of essential health services has now been ensured for 70 percent of the population, average life expectancy has reached 61.9, and primary healthcare network for the rural population has expanded through the establishment of Primary Healthcare Centres (PHCs) and sub-health posts at election constituency level and VDC level respectively. A national drug finance policy and legislation on human organ transplant and anti-biotic policy have also contributed for the improvement of public health. However, there are much more for the government and stakeholders to do to improve the health status. The major problems related to public health include lack of regular adequate human resource, limited supply of drugs and equipments at the community level; lack of effective monitoring and evaluation of access to and standards of health services; lack of management of proper human resources; and inequitable provision of health services. Similarly, major challenges include difficulty with provision of essential services to the targeted group equitably because of geographical difficulty, pressure of population growth, backwardness, poverty, illiteracy and also the ongoing conflict in the country.¹⁵

3.1.2 Major diseases

Malaria is a major vector-borne disease prevalent in 65 districts. Diarrhea, acute respiratory infections (ARI), and measles are other major diseases. Infectious disease and nutritional deficiencies are major causes of child morbidity, disability, and mortality. More than 20,000 children die of diarrhea-related disease every year. ARI is a severe health problem among children under 5, and is responsible for many deaths. Some polio and typhoid infections are also common but not severe. It has been estimated that heart disease could be another major killer in the next 15 years; with 50 percent of the total number of deaths being from heart ailments (DDA, APPON, Matrix and Cygnus 2004).

Although the estimated prevalence rate of HIV infection is 0.5 percent in the age group 15-49, with a male to female ration of 3 to 1, epidemiological data suggests that Nepal has entered the stage of a concentrated epidemic. This means that the HIV/AIDS prevalence consistently exceeds 5 percent in some sub-populations such as Female Sex Workers (FSW) and Injecting Drug Users (IDU). Among high-risk groups, seasonal labour migrants make up 40 percent of the national's HIV infected population, followed by clients of sex workers (18 percent). The number of children orphaned by HIV/AIDS is estimated to be 13,000 (NPC and UNDP 2005). Many Nepalese are also infected with tuberculosis (TB) and according to a 2002 study of the World Bank, and about 44,000 develop 'active' TB every year, leading to 8000 to 11,000 TB deaths a year. A TB prevention programme has been under way since 1996 (EIU 2004).

¹⁵ Based on a draft report of the WHO Nepal office.

3.1.3 Pharmaceutical market and drug consumption

Nepal pharmaceutical market was worth NRs. 6 billion in 2004, of which domestic manufacturers had a 25 percent to 27 percent market share, with the remainder being dominated by imported Indian medicines. The country is importing medicines from nearly 250 pharmaceutical companies, out of which 170 are Indian. Nepal also imports medicines from China, Belgium, South Korea, Australia, Denmark, Holland, and Switzerland. At present, the Nepalese pharmaceutical companies are producing 200 different types of medicines. A total of 39 allopathic pharmaceutical companies, 26 ayurvedic companies, 2350 medical wholesalers, and 18,255 pharmacies are currently operating in the country. Despite a massive upgrade in production quality based on WHO standards, the pharmaceutical companies have failed to expand their share in the domestic market. They still need to improve their image in terms of the quality of their products (DDA, APPON, Matrix, and Cygnus 2004).

The annual increment of drug consumption in Nepal has been recorded at 18.8 percent. Amoxicillin is the highest selling drug from the domestic industries; and vitamins are the highest selling imported drug. The major selling drugs from domestic manufacturers are amoxicillin, vitamins, cough preparations, ciprofloxacin, ibuprofen+paracetamol, ampicillin+cloxacillin, iron preparations, oral dehydration solutions (ORS), paracetamol, metronidazole, albendazole, cotrimoxazole, metronidazole+diloxanide, cold preparations, and tetracycline. Altogether, these 15 drugs constitute a 52.8 percent share in total drug consumption from domestic manufacturers. Similarly, the major selling imported drugs are vitamins, cephalosporins, cough preparations, ciprofloxacin, antacids, ampicillin+cloxacillin, enzymes, calcium preparations, diclifenac, ranitidine, cold preparations, povidon iodine, and cotrimoxazole (Multilateral Trade Integration and Development Project 2005).

3.1.4 Access to health facilities

One of the major problems in providing health facilities is financial: hospitals and clinics charge on a fee-for-service basis, and most Nepalese have neither the insurance nor the funds to pay for healthcare. The government spends about 5 percent of its budget on healthcare, amounting to about US\$ 5 per head annually. Nepal also has privately-run hospitals, but most of them are located in urban centres, and the cost of seeking treatment there is beyond the reach of the majority of the population (EIU 2004). Besides, accessing public healthcare outlets and procuring the drugs they prescribe consumes 59 percent of household expenditure on health. The regional distribution of available facilities is also highly uneven, with the mid-western and far western development regions and mountain ecological belts lagging far behind the others. Life expectancy in the mountain trails that of Terai by seven years; rural people generally live 10 years less than their urban counterparts (UNDP 2004).

3.1.5 Health policies and implementation mechanism¹⁶

With a view to enhancing public health, a National Health Policy was formulated in 1991. It addresses, *inter alia*:

¹⁶ This section is drawn from a study of WHO.

- preventive, promotive and curative health services;
- basic primary health services;
- development of Ayurvedic and other traditional health systems (such as homeopath and naturotherapy);
- community participation in health services;
- human resources for health development;
- resource mobilisation in health services, and inter-sectoral coordination;
- decentralisation and regionalisation;
- improvements in drug supply by enhancing domestic production and upgrading the quality of essential drugs;
- health research.

In line with the National Health Policy, the Eighth Health Plan (1992-1997), Ninth Health Plan (1997-2002), Second Long-term Health Plan (1997-2017) and Drug Policy, 1995 have been framed and implemented. The Drug Policy aims to ensure access to, and quality and rational use of, drugs. Its first amendment in 2001 has sought to address the issue of proper management of prevailing antibiotics uses in food products, animal feeds and agro-substances. As many as 22 drugs are listed as life-saving and emergency drugs. Lists of essential drugs have also been prepared for various health unit levels. The National Ayurvedic Health Policy, 1995 addresses issues of extension of service deliveries and production of Ayurveda medicines from local herbals to minimise imports.

Ministry of Health and Population (MoHP) is the central organisation responsible for the implementation of the health policies and strategies for provision of quality health services. It carries out its responsibility through three departments viz. Department of Health Services, which has five divisions, five centers, five regional health service directorates, and various zonal, district and village level offices and units; Department of Ayurveda, which delivers services through two Ayurveda hospitals, 14 Zonal dispensaries, 35 district Ayurveda health centers and 216 Ayurveda dispensaries; Department of Drug Administration (DDA), which works through its seven sections including Royal Drug Research Laboratory, and three branch offices. In addition, there is one Homeopathic Hospital established in 2012 BS.

The National Planning Commission (NPC) provides overall leadership in ensuring inter-sectoral cooperation for health development. A government/WHO coordination committee also promotes inter-sectoral coordination.

Achievements in policy implementation include adoption of an integrated approach to all programmes, implementation of special programmes such as district health systems development, safe motherhood, community drug schemes, the health management information system, and special surveys to re-evaluate the achievements in the implementation of the health policy. However, there still exist major constraints, which include limited national resources for health services development; centralised administration; ineffective management and supervision; difficult geographic conditions and slow economic growth; weak links existing in inter-sectoral coordination; low priority given to health by other sectoral ministries.

3.2 WTO Commitments and implications on public health

3.2.1 General Agreement on Tariffs and Trade

3.2.1.1 Commitments

As a WTO member, Nepal has to abide by the principles of MFN and national treatment as mentioned in the GATT 1994. The country, therefore, has to treat each trading partner without any discrimination and also has to provide equal treatment to the like products entering into its territory.

Regarding tariffs, the country has bound 99.3 percent of its industrial tariff lines. With regard to agricultural products, all the tariff lines are bound. The country has negotiated an average tariff binding of around 24 percent on industrial goods and 42 percent on agricultural produce. Nepal has opted to apply *ad valorem* duties except on products such as cigarettes, alcohol, petroleum products¹⁷. There are no tariff quotas for imports in effect in Nepal. The current legislation provides for certain tariff exemptions and tariff reductions, in order to facilitate the import of specific goods on a provisional basis.

Tariffs on **public health related products vary but the tariff for medications** has been fixed at 5 percent. Medical equipments for public health projects are exempt from import duties. Other public health related products like tobacco and alcohol are domestically levied with fees like cigarettes and alcohol fee and alcohol control service fee. Nepal has committed to incorporate these fees into custom tariff rates in line with the Understanding on Article II paragraph 1(b) of the GATT 1994. In the revised market access offer on goods, Nepal has confirmed the elimination of other duties and charges (ODCs) for all tariff lines over a period of time between 2-10 years. After that date, all ODCs would be bound at zero.

Regarding trade remedy measures, Nepal has planned to introduce WTO-consistent legislation and regulations on safeguard measures and other trade remedies. Nepal has committed to apply safeguard, anti-dumping and countervailing duty measures only after notifying and implementing laws in conformity with the provisions of WTO Agreements on Safeguards, the Implementation of Article VI of the GATT, and on Subsidies and Countervailing Measures, and that after accession Nepal would apply any such measures only in conformity with the relevant WTO provisions.

3.2.1.2 Implications

In order to comply with the GATT, the country has to implement the MFN and national treatment principles of the agreement. As mentioned earlier, these principles are also mentioned in other WTO agreements, including GATS and TRIPS. Under MFN, If Nepal decides to grant a special benefit to a WTO Member, for example, by lowering customs tariff of a particular pharmaceutical product, it has to extend the similar benefit without any discrimination to other Members as well. Similarly, if other Members decide to offer such benefit to any other Member, Nepal will also get that benefit due to MFN. The MFN principle

¹⁷ Tariffs that are levied as a percentage of the value of the imported product.

can, therefore, imply benefits for Nepal in health related products in terms of equal duties imposed on them. Under the national treatment also, a Member cannot apply internal taxes or other internal charges or quantitative regulations in a manner so as to afford protection to domestic production (Das 1999). This means that Nepalese products would be exposed to stiff competition with foreign products. Therefore, it is of utmost importance for Nepal to enhance the competitiveness of its domestic industries, including pharmaceutical companies, if it has to ensure their sustainability in the globalised world market.

With regard to exceptions provided in GATT Article XX, Nepal can restrict imports or exports from/to specific sources for some specified purposes, e.g., for the protection of human, animal or plant life or health. It gives the country an opportunity to safeguard the health of its people from the imports of products that affect public health. However, whether or not Nepal's existing institutions that deal with such issues have the capacity to identify such risks is a concern. If the country does not justify such restrictions, then it would be subjected to dispute on the ground of the imposition of non-tariff barriers (NTBs).

There is another major concern with regard to such exceptions. Though GATT provides a space for Members to protect their environment and health interests, in some instances, Members may tend to misuse these measures in a way that props up NTBs.¹⁸ Due to this, there is a threat of the imposition of NTBs on Nepalese exports, including pharmaceutical products. This might affect Nepal's pharmaceutical companies that export their products in other countries and the employment opportunities, affecting the incomes of people, which are important for improving the public health situation.

Relating to trade remedy measures, Nepal can apply these measures when it can prove that it has met the conditions to apply them. These measures will be critical for protecting domestic companies, however, they can also pose challenges. For example, due to cheaper imports of drugs, Nepalese pharmaceutical companies might be affected. This would then impact on the policy of the self-sufficiency on drugs of the country. In such a situation, the country may opt to protect domestic companies but it might lead to rise in prices of the medicines, affecting consumers' affordability to drugs, which, in turn, will create pressures on the public health situation of the country. Likewise, it should also be noted that other countries, where Nepal exports its products can also take these measures if they find that Nepalese companies or industries are affecting their domestic markets. In such cases, Nepalese exports will be hurt, creating problems for the growth of the companies and industries and employment aspects.

¹⁸ Whereas the focus once was on bans, import licensing, quotas and other trade policy measures taken at the border, concerns have changed over time, with increasing importance of less obvious types of non-tariff measures that make market access difficult. These include TBT and other domestic policies in importing countries (www.oecd.org)

3.2.2 General Agreement on Trade in Services

3.2.2.1 Commitments

Nepal has committed to market access and national treatment to foreign service suppliers in 11 sectors and 70 sub-sectors¹⁹ in its Schedule of Specific Commitments on Services.

In business services, which include professional services such as medical and dental services and services provided by midwives, nurses, physiotherapists and para-medical personnel, Nepal has not made any specific commitment in terms of market access or national treatment. However, medical experts of foreign origin are allowed to work in Nepal for one year with the permission of Nepal Medical Council (NMC).

The distribution services include commission agent's services, wholesale and retailing services and franchising. Nepal has not specified any market access limitation in the first three Modes in the commission agent's services and franchising. However, in Mode 3, only through incorporation in Nepal, 51 percent of foreign equity capital is allowed. Foreign equity participation will be increased to 80 percent after five years from the date of accession. Mode 4 remains unbound except as temporary movement and corporate transfers indicated in the horizontal section. Likewise, in wholesale and retailing services, there are no limitations of market access and national treatment in the first three Modes of supply. Mode 4 has been left unbound expect until such time that Nepal grants such rights to any WTO Members in any sub-sector, or until Nepal determines the types of foreign entities, which may provide these services, or that Nepal authorises such rights under its laws and regulations, the supply of these services; whichever is earlier.

In terms of educational services, no limitations of market access or national treatment have been specified in the first three Modes of supply, while Mode 4 is unbound. However, in Mode 3, except for educational services funded from state resources, 51 percent foreign equity participation has been allowed. Commitment to increase the foreign equity to 80 percent after five years from the date of accession has also been made.

“Life, accident and health insurance” services are covered by financial services. Nepal has not specified market access and national treatment limitations in the first three Modes of supply and Mode 4 has been left unbound. In Mode 3, all the commitments are subject to entry requirements, domestic laws, rules and regulations and the terms and conditions of the Nepal Rastra Bank, Insurance Board and any other competent authority in Nepal. The commitments in Insurance services are given to the nationals and financial institutions of the Members whose law and policies do not bar the provision of similar commitments to the Nepalese nationals and financial institutions. Such limitations will exist only till 1 March 2004. Insurance services providers will be allowed to open branches only from 1 January 2010. Total foreign shareholding in any institution providing financial services is limited to 67 percent of the issued share capital and the Members of the Board of Directors will be in proportion to equity representation of that service supplier.

¹⁹ The WTO has categorised services into 12 sectors and 155 sub-sectors

Nepal has also made commitment in health related and social services. Commitment has only been specified in “hospital services” while “other human health services” have not been included in the Schedule of Specific Commitments. In hospital services, maximum foreign equity capital of 51 percent has been allowed with Mode 4 left unbound except as indicated in the horizontal section. In the other three Modes of supply, no limitation of market access and national treatment has been specified.

Environmental services include sewage services, refuse disposal services, sanitation and similar services, cleaning of exhaust gases, noise abatement services, nature and landscape protection services. Nepal has allowed 51 percent foreign equity with a commitment of increasing it to 80 percent after five years from the date of accession. Like in other services, Mode 4 has been left unbound while the market access and national treatment limitation has not been specified in other 3 Modes of supply.

3.2.2.2 Implications

Liberalisation of health related services, especially in the context of countries like Nepal possess the opportunities as well as risks (see Table 3.1). Increase in foreign investment in medical facilities, hospital operation, etc., can improve health care facilities and provide greater access to health facilities. People can avail such facilities in their own country and will not have to travel abroad for the same. Better health care facilities can rather attract foreigners into the country for medical services; contributing to domestic employment and income. This can have a dynamic effect with respect to improvement of living standard of the people. Improved living conditions and enhanced purchasing power can contribute to an overall improvement in the public health scenario. The growth of modern health care facilities can also offer attractive employment and income alternatives to the medical professionals, preventing the threat of brain-drain.

Table 3.1: Modes of service supply under GATS and health opportunities and risks		
Supply Modes	Opportunities	Risks
<i>Mode 1: Cross-border supply of services (telemedicine, e-health)</i>	Increased care to remote and under-served areas	Reliability of the supply of such health services can be questionable
<i>Mode 2: Consumption of services abroad (patients travelling abroad for hospital treatment)</i>	Generates foreign exchange earnings for health services of importing country	Crowding out of local population and diversion of resources to service foreign nationals
<i>Mode 3: Commercial presence (establishment of health facilities in other countries)</i>	Creates opportunities for new employment and access to new technologies	Development of two-tiered health system with an internal brain drain
<i>Mode 4: Movement of natural persons (doctors or nurses practicing in other countries)</i>	Economic gains from remittances of health care personnel working overseas	Permanent outflow of health personnel, with loss of investment in educating and training such personnel and shortage of health professional
<i>Adapted from: WHO. 2004. GATS and Health Related Services. Trade and Health Notes.</i>		

On the other hand, increased FDI in health sector can also create disparities due to the exorbitant cost of such services. Since a majority of population is poor in Nepal, health care

facilities provided by profit-oriented private suppliers seem unaffordable. Likewise, such service providers may offer better opportunities and remuneration to the medical personnel, which may cause dearth of qualified personnel in the public sector. Migration of medical professionals to other countries can also create a shortage of such human resources. Apart from the loss of service providers, the government also loses the investment made on training and education of such migrating health professionals. Since health services are publicly funded in most countries, liberalisation of health-related services is viewed by public health advocates as being beneficial only to the developed countries. Though most of the problems can be addressed through appropriate regulations, weak enforcement capacity in most of the poorer countries can jeopardise such endeavours. Therefore, Nepal has to be very cautious about this issue. For a detailed impact on the health related sectors of Nepal, please refer to the policy challenges section on GATS.

3.2.3 Agreement on the Application of Sanitary and Phytosanitary Measures

3.2.3.1 Commitments

Nepal has committed to fully implement the SPS Agreement by the end of 2006. In order to safeguard life or health of human, animals and plants from food borne diseases or pests, various acts have been enforced by the government. Plant Protection Act, 1972 and Plant Protection Rules, 1974 are implemented to save plant life and flora. Minimum standards are fixed for agriculture products (food products and animal feed), which are controlled under the Food Act, 1967 and Food Rules, 1970 and the Animal Concentrates Act, 1976. The Contagious or Infectious Disease Act, 1963 authorises the government to intercept or quarantine any person, animal products, and feeds suspected of carrying an infectious disease at the entry points. The Department of Food Technology and Quality Control (DFTQC) is responsible to implement the laws in association with the local administration. Likewise, DDA is responsible for implementing the National Drug Policy, 1995 with an objective of "Health for All".

The policy has emphasised on the maintenance, safeguarding and promotion of the health of people by making the country self-reliant in drug production. It aims at ensuring the availability of sale of effective, standard, and quality drugs at affordable price in quantities sufficient to cover the needs of the country, and to cover effectively all the drug-related activities including production, import, export, storage, safety, supply and distribution. MoHP has laid down standards for all the medicines imported into the country while Department of Industry (DoI) has taken up the responsibility of enforcing the industrial property rights in respect of pharmaceuticals. In order to fully implement the SPS Agreement, the country needs to seek technical inputs in terms of quality drug production and assurance; lower custom duties on the importation of raw materials, machinery and analytical instruments; and foreign currency required for purchasing raw materials and machinery. Likewise, Nepal has banned 22 pesticides and five industrial chemicals to protect the health and environment from harmful effects of the pesticides and industrial hazardous chemicals.

For the harmonisation of SPS measures, the WTO has encouraged its Members to use international standards, guidelines and recommendations where they exist. In this context, Nepal has also adopted international standards. Nepal has adhered to the International Plant Protection Convention (IPPC) executed and administered by FAO. Nepal is a member of the

Asia Pacific Plant Protection Commission (APPPC), World Organisation for Animal Health (OIE) and Codex. Nepal assured at the time of accession its commitment to adopt all the sanitary measures in relation to equity, transparency, harmonisation, adoption of regional conditions, risk assessment, and control inspection and approval procedures, and also for the administration and implementation with all WTO Members. To fulfil such commitments, Nepal lacks technical expertise and resources, yet Nepal has committed to give priority to the strengthening of the plant and animal quarantine service in the country to make SPS measures consistent with WTO obligations.

Nepal has committed to amend Plant Protection Act, 1972, Plant Protection Regulation, 1975, and Seed Act, 1998. Membership in IPPC, and Decision on the Establishment of Inquiry Points were also committed prior to the accession. In the action plan for the implementation of the SPS Agreement, Nepal has committed to acquire equipment and train SPS enquiry point personnel. To ensure that regulations are based on risk assessments and sufficient scientific evidence, all existing regulations and new amendments were assured of revision. Meanwhile, Nepal will obtain and utilise technical assistance to fully implement the obligations of the agreement. Nepal assured that measures in place already consistent with the provisions of the agreement would not be subject to transitions, and Nepal would ensure that any changes made in its laws, regulations and practice during the transition period would not result in a lesser degree of consistency with the provisions of the agreement than existed on the date of accession. Technical regulations and other measures adopted during this period would be developed in conformity with the provisions of the agreement.

3.2.3.2 Implications

The DDA conducts inspection of the drugs in local market and licensing of pharmaceutical companies. In FY 2060/61, 11 products of six domestic companies and five products of two foreign companies were recalled from market for non-compliance of the standards prescribed by the DDA. The DDA awarded the certificate of good manufacturing practice (GMP) as recommended by the WHO to five domestic pharmaceutical companies recently. This certification provides an opportunity for export of pharmaceutical products from Nepal. The country in its accession package had committed in accordance with the objectives of “Health for All” to emphasise on the maintenance, safeguarding and promotion of the health of people by making the country self-reliant in drug production. According to the DDA, as of 2060/61 BS, 65 (39 allopathic and 26 traditional) domestic drug industries were in operation (Department of Drug Administration 2004)

The Nepalese products are exported to the international market. In order to meet the international standards of similar products, the Nepalese companies need to maintain quality and competitiveness. Apart from competition, every country has regulations formulated to protect the life and health of human, plants and animals in the importing country. For example, the Nepalese food products and drugs have to comply with the Food and Drug Administration (FDA) standards to enter the US market. Hence, the Nepalese producers must have the knowledge of the international standards and must meet the quality standard required for export.

Nepal also imports food commodities and medicines from the neighboring as well as other countries. Import of quality food and drugs into the country will have direct implications on

public health. Since SPS measures require scientific evidences to restrict any product entering the local market; Nepal requires well-equipped laboratory, scientific equipments and efficient human resources to assess the risk carried by such products and impose SPS measures to restrict the trade of those products that affect public health. The implementation of SPS measures, however, demands huge cost and extensive investment in different areas. For an LDC like Nepal, compliance to SPS measures requires upgrading and strengthening of its laboratories, quarantine units and human resources. Technical and financial assistance is required to develop SPS standards.

3.2.4 Agreement on Technical Barriers to Trade

3.2.4.1 Commitments

Nepal has devised Nepal Standards (Certification Mark) Act, 1980 and Standard Weights and Measures Act, 1968. These laws allow laboratories to carry out tests that can determine if technical standards have been met according to the TBT agreement. Nepal Council of Standards (NCS) is authorised to determine standards for goods and services. NCS sets standards according to international standards as well as domestic requirements. A technical committee is set up within NCS to set standards. Nepal Bureau of Standards and Metrology (NBSM) provides explanation for all standards and technical regulations except health and food products. It also looks after all compulsory certification activities. Some laws relevant to technical requirements and councils that maintain standards according to these requirements have been in place in Nepal but they have not been aligned to the requirements of various WTO agreements.

Nepal has, therefore, committed to make changes to the above mentioned standards regime. These amendments also include Nepal Standards (Certification Mark) Act, 1980 and the Regulations, 1982. These changes are required to bring these laws into complete compliance with TBT. In doing so, an enquiry point has been established in NBSM. Nepal has committed to implement the TBT agreement by 31 December 2006 including compliance with the Code of Good Practice by that date.

From the date of accession to 1 January 2007, Nepal has committed to provide MFN and national treatment to all imports that are relevant to technical regulations, standards and conformity assessment procedures. Technical regulations that are already in place within the country have to be notified to the Committee on TBT and the Committee then reviews whether these regulations are in line with WTO requirements. Any additional standards or technical regulations that are adopted until 1 January 2007 must be developed according to the provisions of the TBT agreement. It has also agreed to participate in the work of the Committee on TBT.

Nepal has sought technical assistance to develop its technical infrastructure for regulatory and implementation purposes²⁰. Since technical aptitude forms the basis of the TBT agreement, technical assistance is important for Nepal to enhance its technical skills. Nepal has also opted to train its technical personnel as well as improve documentation procedures of publications

²⁰ With regard to the implementation of the SPS agreement too, Nepal has sought technical assistance in the same manner.

that are dedicated to inform businesses and consumers about the standards that are being used. Accordingly, a journal or a website is to be used to disperse information about technical standards for all products and services in line with the TBT agreement.

3.2.4.2 Implications

Standards help in protecting public health in a number of ways. The formulation of international standards encourages the adoption of a specific benchmark. That benchmark unifies the diversity that may exist between countries regarding standards and can allow unrestricted trade, particularly amongst WTO Members. But the adoption of international standards is not mandatory and since Members can adopt their own levels of domestic protection, it makes the issues of TBT more arduous. Different countries are at different levels of economical and technological progress and thus, formulate domestic standards in line with their technical aptitude. International standards are generally formulated with the technical assistance of developed countries and the benchmark of “quality” is determined by their standards and technological and scientific progress. Agreements like TBT can create problems for developing countries.²¹

Developing countries and the LDCs, including Nepal, have very little say in the determination of standards. In such circumstances, the same applies to them when they formulate their domestic standards because determining a standard for themselves requires technological know-how that meets the match of international standards or are better than international standards. This, in turn, requires scientific justification. From the outset, TBT can raise standards for health related products in this regard and international standards can improve the quality of public health products, particularly for import driven countries like Nepal.

Under TBT, Nepal retains the right to restrict trade but it has to do so with justification for the protection of human health or safety, protection of animal or plant life, protection of the environment, national security interests or the prevention of deceptive practices. Due to the lack of a general as well as technical infrastructure, how this protection will be sought is questionable. This means that regulation of imports for health related products, particularly the importation and consumption of medication is limited. In such circumstances, the ability to regulate standards for nutritional content in food, toxic materials, etc. also becomes limited.

From the export perspective too, there are some concerns for Nepal. Nepal’s exports can be banned on grounds of TBT principles. The TBT measures can work as NTBs for the Nepalese exports and can be adopted by other countries by using the tripartite definition of the TBT Agreement in technical regulations²², standards²³ and conformity assessment procedure²⁴.

²¹ They establish standards that were set without consulting most of them; they impose huge implementation costs and when used as tools of protection, they can drag countries into protracted disputes involving substantial legal and administrative costs (<http://www.rbf.org/pdf/17-chapter%2017.pdf>).

²² Document which lays down product characteristics or their related processes and production methods...with compliance is mandatory (University of Lausanne, 14-18 June, 2004).

In this context, there are some challenges too. Nepal's problem lies in addressing TBT issues since it does not have proper legal and policy frameworks and well-equipped institutions. There is also a very low level of awareness of the TBT agreement within private and public sectors.²⁵ Without understanding the TBT mechanism and legal flexibilities it allows, it is not possible to frame a legislative framework for its application nor does it facilitate in specifying the kind or type of technical assistance required to implement the TBT agreement. Besides, though technical assistance has been sought in order to implement the agreement, there is a lack of clarity in the kind of technical assistance required and given. Much needs to be done in this direction. And the other most important aspect is the cost of implementation. Although formulating standards is the basic requirement to facilitate international trade, the actual cost of formulating and implementing standards can turn out to be so costly that Nepal might fail to adhere to the norms of TBT.

3.2.5 Trade Related Aspects of Intellectual Property Rights

3.2.5.1 Commitments

Nepal has committed to implement TRIPS by no later than 1 January 2007. However, in the case of the LDCs, the transition period has been recently extended, i.e., until 2013 through a decision recently made at the WTO in December 2005. Keeping in consideration the Doha Declaration, as an LDC member, Nepal will have to grant patent protection to pharmaceutical products by 2016. Regarding other commitments, Nepal has to amend Copyright Act, 2002 and Patent, Design and Trademark Act, 1965. In the existing legislation for patent, there are no provisions for compulsory licensing.

In order to comply with TRIPS provisions and use its flexibilities, Nepal had committed to develop an Industrial Property (Protection) Act by no later than 1 January 2006; and the deadline has been missed. Nepal is a member of World Intellectual Property Organisation (WIPO)²⁶ since 4 February 1997 and Paris Convention²⁷ since 22 June 2001. Nepal has made commitment to participate in Berne Convention²⁸, Rome Convention, and Treaty on Intellectual Property in Respect of Integrated Circuits by no later than 1 January 2006.

²³ Document approved by a recognised body that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. Ibid.

²⁴ Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled. Ibid.

²⁵ It was recognised that the implementation of the TBT Agreement involved different institutions and competencies, both at public and private level (TWE No 276, 1-15 March, 2002).

²⁶ It deals with all the treaties and conventions on IPRs and came into being in 1967.

²⁷ It deals with the protection of industrial property rights and came into being in 1883.

²⁸ It deals with rights concerning artistic and literary works and came into being in 1886.

Besides, Nepal has committed to enact a plant variety protection law and amend judicial administration law, appellate court regulation and procedural law for compliance with TRIPS in respect of civil and judicial procedures and remedies, criminal procedures, etc.

Upon accession, Nepal has committed to establish MFN and national treatment in all areas covered by TRIPS, in particular in the following areas: extension in the Copyright Act, 2002 of protection to foreign works on a full national treatment basis; and the elimination of discrimination in fees charged foreign vs. domestic applicants. Also, Nepal has committed to establish and strengthen Nepal Copyright Registrar Office; and establish Trademark Information Centre; Industrial Design Information Centre; Industrial Patent Information Centre; and Layout-designs Information Centre.

3.2.5.2 Implications

There is a growing concern that the monopoly situation created by the patents on pharmaceutical products would lead to increases in drug prices. Since over 90 percent of the drugs on the WHO's "essential drugs list" are off-patent and a study on drug prescribing practices in Nepal shows that 86 percent of prescribed drugs are from the essential drugs list (Multilateral Trade Integration and Development Project 2005), it cannot be concluded that the patenting of pharmaceutical products under TRIPS would result in an increase in the price of all drugs.

However, a few points are important to note here. First, there is a greater chance of an increment in the price of the remaining 14 percent of drugs, which are excluded from the essential drugs list. Secondly, while drug prices for the new and existing (known) diseases such as HIV/AIDS are already higher, there is every possibility that the drug prices for the new and emerging (unknown) diseases will also rise due to intellectual property protection. Thirdly, even in the case of 86 percent of the drugs prescribed under the essential drugs list, there can be an increase in the price of the drugs if new and more effective drugs enter the market replacing the drugs under the essential drugs list.

Therefore, the global negotiations dealing with pharmaceutical product patents and public health at the WTO level are a matter of concern for Nepal too. While enacting intellectual property laws at the domestic level, as required by TRIPS, Nepal has to make maximum use of TRIPS' flexibilities to minimise the harms of intellectual property protection on pharmaceutical products. Focus should also be given to research and development (R&D). This would not only strengthen the capacity of the domestic companies to manufacture more effective drugs but would also be instrumental in capitalising on the vast amount of medicinal plants that the country possesses. The financial and technical resources required for R&D are, however, a concern for the country. Nepal can seek financial and technical assistance in this regard.

3.3 WTO agreements and policy issues/priorities for Nepal

3.3.1 Policy flexibilities

3.3.1.1 General Agreement on Tariffs and Trade

Nepal has bound the tariffs of pharmaceutical products at 20-30 percent. The applied rates for these products at present are normally at 5 percent. As per the GATT, the country has the flexibility to raise the tariff rates of these products up to the bound rates. Besides, the agreement allows Nepal to make use of trade remedy measures and also the exceptions relating to health when pertinent. By adopting the safeguard, anti-dumping and countervailing measures, Nepal can provide protection to its domestic pharmaceutical companies. It can even raise tariffs above the bound rates, under particular circumstances. In the Report of the Working Party on the Accession of Nepal, the country has already made commitments to devise laws relating to such trade remedy measures.

With regard to health exceptions, the country has the flexibility to put a ban on the imports of products that affect public health. It can, for example, put a ban on the import of counterfeit²⁹ medicines³⁰ or on the import of any other product that negatively affect public health in Nepal.

3.3.1.2 General Agreement on Trade in Services

In key areas of GATS, governments face choices about the breadth and depth of liberalisation of trade in health related services and the impact of such liberalisation on health policy. In fact, countries are free to decide whether liberalisation in the health sector should be pursued or not and to what extent. Countries are not obliged to liberalise health services if they do not wish to do so. These choices make it imperative that health officials understand the structure and substance of GATS, collaborate with other government agencies on GATS implementation and liberalisation, and act to ensure that the GATS process does not adversely affect national health policy (WHO 2004). The health officials in Nepal can also work on this aspect for further liberalisation of services sectors and on the aspects of Nepal's commitment under GATS, which has been explained above.

From the public health perspective, Article XIV of GATS has empowered Members to take measure necessary to protect human, animal or plant life or health regardless of their obligation under the agreement. This means that Nepal can regulate trade in services on grounds of public health, despite its commitment in different sectors and sub-sectors.

²⁹ According to WHO, a counterfeit medicine is one, which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with incorrect quantity of active ingredients or with fake packaging. This definition includes intellectual property and non-intellectual property elements.

³⁰ The regulations or restrictions on the importation of counterfeit medicines can also be done under the TBT Agreement.

3.3.1.3 Agreement on the Application of Sanitary and Phytosanitary Measures

Due to the SPS agreement, Nepal has got the legal basis to restrict trade to ensure food safety, and protection of human life from plant or animal carried disease. In order to safeguard life or health of human, animals and plants from food borne diseases or pests, the SPS agreement provides Nepal a flexibility to apply SPS measures on the imports of products, however, under particular circumstances. The agreement requires Members to apply such measures based on the scientific principle supported by sufficient scientific evidence. When existing scientific evidence is insufficient to determine risk, Members can provisionally adopt SPS measures on the basis of available pertinent information, including that from the relevant international organisations as well as from SPS measures applied by other Members³¹.

Since Nepal has committed to implement the agreement by 2006, till this period, the country has the flexibility to set its national standards for products and enforce them for safety of human, plant and animal life or health. WTO Members, including Nepal, are also allowed to set higher standards based on appropriate assessment of risks so long as the approach is consistent and not arbitrary. In this regard, Nepal has to amend the existing laws and regulations (for example, Plant Protection Act and Seed Act) to comply with SPS measures.

Since the implementation of the agreement requires huge amount of financial and technical resources, the country needs to seek financial and technical assistance. It is interesting to note that Nepal has already sought for such assistance for implementing this agreement and other agreements in the Report of the Working Party on the Accession of Nepal (See Box 3.1). Hence, Nepal should make effort to capitalise on such aspects and seek technical assistance, for example, for strengthening the laboratories for testing the quality of food products. The concerned government authorities should also seek technical assistance for the strengthening of the enquiry point, i.e., DFTQC (in terms of human resources development and other institutional aspects) so that it is enabled to properly deal with SPS issues.

Box 3.1: Technical assistance in the Report of the Working Party on the Accession of Nepal

The section of technical assistance, mentioned in paragraph 152 of the Report of the Working Party on the Accession of Nepal, stipulates, "...as a least developed country with limited resources, infrastructure and institutional and technical capabilities, Nepal would face serious difficulties to implement the WTO Agreements expeditiously by its own means. In the Legislative Action Plan and in the various action plans..., Nepal had identified the specific areas and projects where technical assistance would be welcome, and asked that specific offers of assistance in these areas would be forthcoming. In the view of Nepal it was of the utmost importance, that individual WTO Members, bilateral donors, international agencies and the WTO Secretariat coordinate their responses to the technical assistance requested as soon as possible. From Nepal's perspective, WTO Members clearly had an interest in working with Nepal to ensure that action plan timetables were met. He noted that a Member had offered to assist in the implementation of some aspects of the TRIPS Agreement. Another Member had offered to assist in the development of institutional capabilities concerning transparency, notifications and judicial review. Nepal believed that additional technical assistance would be required with respect to these and other areas of WTO implementation as noted in the action plans.

³¹ Members can accept the SPS measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same products.

3.3.1.4 Agreement on Technical Barriers to Trade

The agreement has provided Nepal the right to restrict trade for “legitimate objectives”. Legitimate objectives include protection of human health or safety; protection of animal or plant life or health; protection of the environment and national security interests; and prevention of deceptive practices. This agreement gives Nepal an opportunity to enforce laws and regulations, which could also restrict trade for health reasons provided measures taken do not create unnecessary obstacles to trade. Since the agreement has recognised individual country’s rights to adopt domestic standards, which they consider appropriate in order to safeguard human, animal, plant life or to protect the environment, Nepal can develop its own standards. Based on its standards, it can restrict the import of products that negatively impact on public health, such as counterfeit drugs that enter the market with spurious labeling. Nepal has committed to implement the agreement by 2006.

Since the agreement has recognised the problems that countries like Nepal face while complying with its provisions. It has, therefore, provisioned for the special and differential treatments (S&DTs) to countries like Nepal. The country can capitalise on such treatments. For example, the agreement has requested Members to provide technical assistance to such Members in any or all areas covered by the provisions of the agreement, urging them to take into account the special development, financial and trade needs of developing country Members like Nepal. In order to implement the agreement, the country can seek technical assistance from individual WTO Members, bilateral donors, international agencies, etc. The concerned government authorities should also seek technical assistance for the strengthening of the enquiry point, i.e., NBSM, which looks after technical regulations and standards in the country.

3.3.1.5 Agreement on Trade Related Aspects of Intellectual Property Rights

Nepal has to comply with TRIPS provisions³², while amending the existing or enacting the new laws for intellectual property protection, for example, it has to introduce the new Acts such as Industrial Property Act and Plant Variety Protection Act³³. While devising such legal frameworks, Nepal can capitalise on the flexibilities the agreement has provided to its Members, for example, flexibilities on compulsory licensing and parallel import. Nepal can incorporate these flexibilities as strong provisions in its domestic IPR laws such as in the Drug Act and the Industrial Property Act.

Since TRIPS, in its Article 66 and 67, provisions for transfer of technology and technical and financial cooperation to the LDC Members, the country has the flexibility to obtain such benefits, provided other Members consider Nepal’s request for technology transfer and technical and financial cooperation and work in line with the spirit of TRIPS. Along with TRIPS, there are also other agreements and decisions that call for technology transfer to countries like Nepal (See Box 3.2).

³² In the accession deal, Nepal has committed to implement TRIPS by 2006. However, a recent decision of December 2005 has extended the transition period for the implementation of TRIPS until 2013. In the case of patent protection to pharmaceutical products, the transition period for the LDCs is 2016.

³³ As a *sui generis* (of its own kind) option, which is a flexibility provided by TRIPS.

Box 3.2: Technology transfer flexibilities for Nepal

The willingness of developed countries to facilitate access to and transfer of technologies to developing countries has been reflected in a number of international agreements. For instance, there are some important WTO agreements that call for technology transfer to developing and least developed countries. GATS acknowledges that the increased participation of developing country members in world trade shall be facilitated through, *inter alia*, access to technology on a commercial basis and further calls on members to encourage foreign suppliers of telecommunication services to “assist” in the transfer of technology, training and other activities that support the development of their telecommunications infrastructure and expansion of their telecommunications services trade. TRIPS calls upon developed countries to “provide incentives to enterprises and institutions” in their territories to transfer technologies to LDCs. Although the nature of such incentives is not defined, the measures are supposed to enable LDCs “to create a sound and viable technological base”. Similarly, the Doha Declaration³⁴ has introduced a binding mandate for WTO members to examine the relationship between trade and technology transfer. To this end, ministers have established a Working Group on Trade and Transfer of Technology.

Despite these initiatives, some developed countries tend to perceive the Doha mandate as an academic exercise and are reluctant to deepen the work towards the implementation of technology transfer clauses in WTO agreements or to initiate negotiations for increasing technology transfer flows. In this context, Nepal should urge WTO members and the development partners to realise the importance of transfer and diffusion of technologies for the country, and call for making actions as stipulated in the Brussels Programme of Action for the Least Developed Countries.

Adapted from: NPC and UNDP. 2005. *Nepal Millennium Development Goals Progress Report 2005*. Kathmandu: National Planning Commission and United Nations Development Programme.

Within TRIPS, there is also a “Bolar” provision, which gives permission to researchers to use a patented invention for research, in order to understand the invention more fully. This provision allows testing and regulatory approval of generic version of a drug before its patent expires. After the transition period for pharmaceutical product patent for Nepal³⁵ expires in 2016, this provision can be used. For instance, the government can encourage the domestic public and private sector institutions such as Singh Durbar Vaidya Khana, Royal Drug Research Laboratory or a private drug company to use this provision. At the same time, during this transition period, the government has to encourage and support the companies to produce generic versions of the patented drugs. The agreement also deals with anti-competitive practices. The provision concerning this mentions that governments can act, again subject to certain conditions, to prevent patent owners and other holders of IPRs from abusing IPRs, ‘unreasonably’ restraining trade, or hampering the international transfer of technology. Therefore, in cases of abuse of IPRs by the patent owners, Nepal too can use this exception.

³⁴ The Doha Declaration was adopted by WTO Members in 2001 during the fourth Ministerial Conference of the WTO in Doha.

³⁵ According to the Doha Declaration on TRIPS and Public Health, the LDC Members of the WTO are not required to provide pharmaceutical product patent until 2016.

3.3.2 Policy challenges

3.3.2.1 General Agreement on Tariffs and Trade

Since Nepal has bound the tariffs of pharmaceutical products at 20-30 percent, there is no problem for the country to increase the applied tariffs up to the level of bound rates, if the government decides to do so for protecting the domestic pharmaceutical product companies in the post WTO era. However, at the same time, such a protection can affect consumers. For example, if the government increases the applied tariff of a particular drug up to the bound rate, i.e., for instance from 6 percent to 28 percent, the price of that drug will increase in the domestic market, thus making the drug expensive and unaffordable. Therefore, it is a challenge for the country to take a balanced approach.

For wider interest of the consumers, the country can only increase the tariffs on those products, which are widely produced and available in Nepal. However, even in this case, two things are important to note from the public health perspective. First, the concerned regulatory bodies of the government should be able to monitor the practices in the market after protection to the domestic companies is provided. For example, few companies producing those medicines can increase the prices of the product on an unreasonable basis. To regulate such practices, it is encouraging that the government is considering to introduce a Competition Act in the country³⁶. Second, before providing such protection to the domestic companies, there should be an analysis of quality aspects of both – the imported products and the domestic products. The government has to take into account whether or not such protection would force the consumers to consume the low quality products.

Similarly, the principles of non-discrimination (MFN and national treatment) under the GATT can also put challenges on the policy aspects of Nepal. For example, it should provide no less favourable treatment to the like products (for instance like drugs) of other Members in the domestic market. This means a tough competition with the products of the foreign companies and further pressure on the domestic companies. In particular, this can also affect the health policy of self-sufficiency on drugs, as domestic drug manufacturers might face difficulties to sustain in the market. Besides, the country has committed to phase out ODCs within 2 to 10 year period, which means that there will be no room for the government to continue to impose ODCs after a period of 10 years as all ODCs would be bound at zero. Therefore, in future, ODCs would not help the country to generate revenue for the economy.

Under the GATT, the government can also take the safeguard, anti-dumping and countervailing measures to safeguard the domestic companies, but these measures can also lead to rise in prices of the products. With regard to exceptions, the country has the flexibility to put a ban on the imports of products that affect public health but in some particular cases, it will be a difficult task for least developed Members like Nepal to identify such risks on public health as the country lacks human resources, technical and financial resources and the well-equipped institutions to gather such information and take decisions.

³⁶ Under a voluntary commitment made in the Report of the Working Party on the Accession of Nepal, Ministry of Industry, Commerce and Supplies (MoICS) has prepared a draft bill with the support of UNDP's project on Multilateral Trade Integration and Human Development.

Also, there is another major concern with regard to such exceptions. Other Members of the WTO may tend to misuse these exceptions and impose disguise form of barriers to trade (for example, NTBs) on the exports of Nepalese pharmaceutical products. This might affect Nepal's pharmaceutical business and the employment opportunities, affecting the incomes of people, which are important for improving the public health situation. Moreover, the application of health exception requires scientific justification, without which no Member can impose import restrictions. Due to its technical ineptitude, the application of this measure might not be applicable for Nepal. Given these challenges, Nepal has to seek technical assistance from other Members, but since WTO Members are not willing to provide technical assistance in a manner they have committed or the WTO agreements have provisioned, Nepal has to make concrete efforts to seek such assistance. The recently concluded sixth Ministerial of the WTO in Hong Kong in December 2005 has called upon WTO Members to provide "Aid for Trade" for countries like Nepal. The country has to develop a national strategy to garner the benefits from such schemes.

3.3.2.2 General Agreement on Trade in Services

Nepal has made commitments in various services sectors, which have direct or indirect implications on public health. Business services and health related and social services are sectors where GATS can directly affect the health services. Professional services such as medical and dental services and services provided by midwives, nurses, physiotherapists and para-medical are not scheduled in the specific commitment. However, non-scheduling or non-commitment in the sub-sector leaves space for the government to analyse the impact of liberalising them and formulate policies prior to the request offer approach with other WTO members. Since Mode 4 is covered under this category, its implications have to be carefully analysed. Nepal has allowed medical experts from other countries to work in Nepal for a year. They require prior registration from NMC. Till December 2005, NMC had given permission to 2,740 foreign doctors to work in Nepal. Likewise, according to the NMC, a total of 5708 doctors³⁷ are registered in Nepal and 14,740 nurses.³⁸ However, due to lack of regulations and records, temporary movement or migration of Nepali health professionals remains unaccounted.

Brain drain of such human resources is seen as a major threat towards provision of effective health services in most developing countries. Given the problem, the value of remittances back is minor in comparison to the loss of potential earnings. In this context, the country not only loses its human resources but also loses investment made on such medical personnel (especially those funded by the government). Nepal continues to experience imbalances in the health workforce due to shortages of personnel and geographical maldistribution. Thus, 18,439 people depend on a doctor (2001/02).³⁹ Concentration of doctors in urban areas (especially Kathmandu Valley) remains as another major problem towards dissemination of quality health services in

³⁷ Nepal Medical Council (NMC). Till 27 December 2005. Total includes MBBS and BDS.

³⁸ Nepal Nursing Council (NNC). 71st list, till 13 December 2005. Total includes Nurses, ANMs and Foreign Nurses. There are 418 foreign Nurses working in Nepal.

³⁹ WHO Regional Office for South-East Asia, Country Health Profiles – Nepal, WHO.

the rural areas of the country. It has been found that the health policy is yet to address this issue.

Nepal has made commitment in hospital services, where foreign investors can invest up to 51 percent. Since, there are no limitations in market access or national treatment, this service is open to all. Foreign investment in hospitals will increase infrastructure, modern equipments necessary for improved health care facilities. Similarly, such facilities will reduce the outflow of people for medical purpose and can even attract foreigners for medical services. The growth of modern hospitals can prevent brain drain, as these facilities can offer alternative employment opportunities. However, focus on health care as an industry may easily lure attention away from the fundamental functions of a health system. The primary purpose of health services is to provide quality care and preventive services to help people to become and stay healthy. Moreover, internal brain-drain (shifting of doctors and nurses from public sector to private sector) can negatively affect the public health services provided by the government body. Since, the government has been catering health services to the poorer sections of the society, scarcity of skilled and qualified medical professionals can be threatening in the long run.

Educational sector has been opened to foreign educational institutions. Nepal has benefited through liberalisation of this sector. As per NMC, out of 15 colleges in the medical sector (12 medical and 3 dental), 9 medical colleges and 2 dental colleges are operating through private or foreign investments. Likewise, according to Nepal Nursing Council (NNC), 40 private and public Nursing Institutes are operating in Nepal. Increased number of medical and nursing institutes will be helpful in producing efficient medical personnel required to provide quality health care. The growth in supply can compensate the loss created by the migration of medical personnel.

Entry into the WTO has opened doors for better insurance schemes to enter Nepal. International companies like American Life Insurance Company (ALICO), and Life Insurance Company Nepal (LIC Nepal) have been providing insurance services in the domestic market. Since Nepal has not laid down complicated limitations in this sector, growth of insurance business in Nepal is imminent. Insurance companies are planning to introduce such packages in Nepal. Currently, 17 Insurance Companies are operating in Nepal as per the norms and values of Insurance Act, 1992, and Insurance Rules, 1993. Among them, two are composite companies transacting Life as well as General Insurance Business, three are Life Insurance Companies and twelve are General Insurance Companies (Nepal Insurance Board). However, since all these companies are concentrated only in the Kathmandu valley and the urban centers, insurance companies are yet to serve the rural people.

Box 3.3: Opportunities and challenges for Nepal under four Modes of services supply

As mentioned above, there are four modes of services supply under GATS, which offer opportunities for Nepal. But how far the country would be able to benefit from the liberalisation under these Modes remains a question given that the country lacks adjustment measures and infrastructure to benefit from them. Besides, these Modes of services supply are not without challenges.

Mode 1 deals with cross border supply of services, for example, telemedicine and e-health. Nepal has not made any concrete policy documents for such services yet. In order to benefit from this Mode, the country needs to prepare policies on such services. This might help in ensuring increased care to remote and under-served areas. However, whether or not such facilities can be provided in the present context of the infrastructure and resources we have is a major concern. Besides, the reliability of such supply of health services is also questionable.

Mode 2 deals with consumption of services abroad, for example, patients travelling abroad for hospital treatment. Nepal remains an LDC with poor health status and limited health treatment opportunities. It might not be able to offer such services in the present context⁴⁰, unless there is vast improvement in the skill enhancement of health professionals and facilities of hospital and other health institutions. If this is done, it will serve the purpose of foreign exchange earnings but it might lead to the diversification of resources for foreign nationals, which could be used for improving public health situation in the remote and inaccessible areas of Nepal. However, with regard to this Mode, Nepal can explore its potential on traditional medicinal plants and their usage. This can attract some patients of foreign countries.

Mode 3 deals with commercial presence, for example, establishment of health facilities in other countries. Given the present situation of Nepal, this also remains a challenge for the country to capitalise on this Mode. If this is done in future, it can create opportunities for new employment and access to new technologies. However, this can also lead to the development of two-tiered health system with an internal brain drain.

Mode 4 deals with temporary movement of natural persons, for example, doctors or nurses practicing in other countries. With regard to this Mode, Nepal has the potential to export its health professionals to other Member countries that liberalise this Mode under GATS. This would ensure economic gains from remittances of health care personnel working overseas. However, this would also lead to permanent outflow of health personnel, with loss of investment in educating and training such personnel. Besides, since WTO Members, mainly the developed ones, are not willing to liberalise this Mode citing reasons of security, whether or not Nepal would benefit in the near future from this Mode remains to be seen. The country has to make alliance with other developing Members, which are demanding for liberalisation of this Mode within GATS.⁴¹ However, one important thing that the government should take note even if this Mode is liberalised is that it will create competition among health professionals among developing Members, including South Asian countries.

⁴⁰ Some patients from few parts of India, however, come for treatment in Nepal.

⁴¹ The LDCs have been demanding that the negotiations under Mode 4 must ensure that administrative procedures and other barriers in developed Members do not impede the full and effective access of service suppliers, in the name of the Economic Needs Test, mutual recognition of qualifications, and implementation of the commitments under GATS including a GATS' visa as regards the supply of services under Mode 4.

Entry of foreign service providers into the environmental service can also benefit the country. Nepal has been facing problems regarding solid waste and hospital waste management, and dumping sites. Foreign participation in such areas can have long term impact on the health of the people living in and around the areas covered by such service providers.

3.3.2.3 Agreement on the Application of Sanitary and Phytosanitary Measures

There are concerns that in the present context, Nepal does not have adequate laws that comply with SPS measures. For example, a study of the WHO indicates that Nepal's Plant Protection Act, 1972 could be outdated and the measures stipulated in the Act could be trade restrictive and subject to disputes. The report states that the government issued the notification prohibiting imports of certain plant or plant products under the same Act around 28 years back but since then, this notification has not been reviewed even once. As the government has committed in the Working Party Report to amend this Act, there should be wider discussions among stakeholders to ensure that the Act complies with SPS and at the same time promotes public health in the country.

With regard to export of Nepalese pharmaceutical products and food items, the quality and the competitiveness of the products matter much. Each Member has regulations formulated to protect the life and health of human, plants and animals. For example, in order to enter the US market, Nepalese products have to comply with the FDA standards. Hence, it is important that the government and the private and business sector pay attention to the international standards and the SPS rules and regulations of other Members. The import of food commodities and medicines from the neighboring as well as other countries also possesses challenges. Since SPS measures demand scientific evidence to restrict any product entering the local market; the country requires well-equipped laboratory, scientific equipments and efficient human resources to assess the risk carried by such products. For Nepal, compliance to SPS measures also demands upgrading and strengthening of its laboratories, quarantine units and human resources. Technical and financial assistance is required to harmonise with international standards so that the country is able to participate in international trade.

Though the country is allowed to determine the standards at the national level, it is a daunting task to set standards and harmonise them with the international standards. This might create a risk for the Nepalese exports as they could be prohibited on grounds of SPS measures. The other dimension of the same aspect is that the SPS measures can be taken as disguised form of protection, for example, as NTBs by other Members. Many developed and developing Members of the WTO have been blamed for imposing such barriers on exports of the LDCs. For example, Norway banned the export of Nepalese honey a couple of years back on the ground that it had high level of pesticide residue (Adhikari and Adhikari 2005).

3.3.2.4 Agreement on Technical Barriers to Trade⁴²

The agreement has provided Nepal the right to restrict trade for the protection of human health or safety; protection of animal or plant life or health; protection of the environment and national security interests; and prevention of deceptive practices. However, the TBT measures taken to

⁴² The challenges due to SPS and TBT agreements are similar in many cases.

restrict trade should not create unnecessary obstacles to trade. The agreement has recognised individual country's rights to adopt domestic standards, which they consider appropriate in order to safeguard human, animal, plant life or to protect the environment. In this case, the government has to set technical regulations and standards for different products. However, determining technical regulations and standards is not an easy task, particularly for countries like Nepal. The cost of formulating and implementing regulations and standards can turn out to be so huge that Nepal might fail to comply with TBT measures. The government needs to seek financial and technical assistance for human resources development, strengthening of institutions dealing with TBT and the enquiry point. The country needs to upgrade its testing as well as calibration facilities. It also has to provide a scheme for the registration and certification of products. There is also a very low level of awareness of the TBT agreement within private and public sectors. The homework also needs to be done in the areas of law and policy making.

3.3.2.5 Agreement on Trade Related Aspects of Intellectual Property Rights

The major policy challenge concerning TRIPS is the harmonisation of national IPR rules with the international ones. As in the case of other agreements, it also demands huge cost for the implementation of the agreement. Nepal has to comply with TRIPS provisions, by amending or introducing the laws for intellectual property protection. Nepal should capitalise on the flexibilities and exceptions provided by the agreement while introducing IPR laws. However, whether or not the country would be able to utilise the flexibilities such as compulsory licensing and parallel import, and the exceptions such as Bolar provision remains a major concern. A lot of policy exercise should be done in this regard. Besides, due to patent protection in future, the prices of the pharmaceutical products, including drugs, might rise, putting pressures on the public health status of the people. This would create problems for the Nepalese to afford drugs and resultantly, the public health situation can worsen.

Due to IPRs, such as patent and plant breeders' rights, farmers' rights in relation to access to seed, traditional knowledge, benefit sharing can be affected⁴³, also putting impacts on their incomes that they need for sustaining their livelihood and maintaining health. Also, most industries and pharmaceutical companies might not be able to benefit from IPRs as the cost of IPR registration is generally high and the process too is very complicated and cumbersome. The Bolar exception could be utilised but it also requires certain prerequisites such as research capacity within the public and private sector institutions and also among the individual experts of the country. In cases of abuse of IPRs by the patent owners, Nepal can use the exception of anti-competitive practices provisioned in the agreement. However, currently Nepal lacks an effective legal framework to see such cases.

The agreement has called for technology transfer to least developed Members like Nepal, however, there has been very little progress from the part of developed Members to help LDC Members. If we see the current trend of FDI inflow and technology transfer in Nepal, out of 991 approved projects, only 5 percent projects are either for "technology only" or "technology and equity category" (NPC and UNDP 2005).

⁴³ The government is currently in the process of enacting Plant Variety Protection Act and Access and Benefit Sharing Act. Both of these Acts deal with traditional knowledge, access to biological resources, benefits arising out of the commercial use of biological resources and sharing of such benefits on a fair and equitable basis.

Annex 1

Matrix of public health policy priorities for Nepal (In reference to five WTO agreements)

	General Agreement on Tariffs and Trade (GATT)	General Agreement on Trade in Services (GATS)	Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)	Agreement on Technical Barriers to Trade (TBT)	Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)
Policy Priorities	<ul style="list-style-type: none"> •Making use of predictability and transparency of the multilateral trading system, such as binding of tariffs •Tariff imposition strategies for the promotion of domestic pharmaceutical companies •Building safety nets for domestic companies and industries through effective laws on trade remedy measures •Strategies for domestic drug production (in terms of quality and competitiveness), keeping in consideration the implications of phase out of other duties and charges 	<ul style="list-style-type: none"> •Under Mode 1: Cross-border supply of health services – consideration over national policy on e-Health; review of prospects or constraints of trade under this Mode, including the review of information technology infrastructure and its potential to contribute to e-Health. •Under Mode 2: Consumption of health services in other countries – preparing the accurate estimates of the scale of movement of nationals to other countries for consumption of health services and review of the problems associated with such movement; preparing the estimates of the scale of movement of foreigners to Nepal for consumption of local health services and review of the prospects in future. •Under Mode 3: Commercial presence of foreign health services providers – preparing the 	<ul style="list-style-type: none"> •Setting national SPS standards •Monitoring export/import of products with regards to SPS •Ensuring that public health is not compromised during export/import •Introducing the new laws and regulations keeping in consideration the SPS compliance issues •Amending the existing laws and regulations for complying with SPS (for example, Food Act, 1972 and Seed Act, 1988) •Strengthening laboratories for testing and inspection •Strengthening enquiry point, i.e., DFQTC •Strengthening institutions (such as DDA, quarantine check posts) 	<ul style="list-style-type: none"> •Setting national TBT regulations and standards •Monitoring export/import of products with regards to TBT •Ensuring that public health is not compromised during export/import •Introducing the new laws and regulations keeping in consideration the TBT compliance issues •Amending the existing laws and regulations for complying with TBT (for example, Nepal Standards (Certification Mark) Act, 1980, and the Regulation, Drug Act?) •Strengthening enquiry point, i.e., NBSM •Strengthening institutions dealing with TBT measures 	<ul style="list-style-type: none"> •Harmonising national IPR regime with TRIPS by enacting and enforcing laws •Capitalising on TRIPS flexibilities (compulsory licensing and parallel import) and exceptions (Bolar provision and provision on anti-competitive practices) while devising laws •Encouraging domestic pharmaceutical companies to produce generic versions of patented drugs until 2016 •Focus on research and development for harnessing the country's potential to produce pharmaceutical products; and enhance the quality of such products •Encouraging institutions and companies to use Bolar provision after transition period for

	General Agreement on Tariffs and Trade (GATT)	General Agreement on Trade in Services (GATS)	Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)	Agreement on Technical Barriers to Trade (TBT)	Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)
	<p>and MFN and national treatment,</p> <ul style="list-style-type: none"> • Planning and strategies development for making use of GATT exceptions • Seeking technical assistance for the implementation of provisions of the agreement, which is also mentioned in the Working Party Report on the Accession of the Kingdom of Nepal. 	<p>estimates of the current status of trade in this Mode; review of the national policy on FDI, with regard to implications on the health sector; estimates of the most important endowments enjoyed by the country in relation to Mode 3.</p> <ul style="list-style-type: none"> • Under Mode 4: Temporary movement of natural persons – preparing the estimates of the scale of movement of health professionals abroad and foreign health professionals to Nepal; Creating favourable government regulations for health professionals to go abroad for jobs and for foreign health professionals coming to Nepal • Strategies to reap benefits and tackle challenges from the country's commitments on each Mode of services supply (<i>as explained in the report</i>), for example strategies to create conducive environment for skilled health professionals to work in Nepal. 	<p>dealing with SPS measures</p> <ul style="list-style-type: none"> • Ensuring that the private sector complies with SPS measures • Making aware the stakeholders of the SPS measures • Seeking technical and financial assistance required for the implementation of SPS • Allocating the budget for the implementation of SPS 	<p>and encouraging pharmaceutical companies to develop their</p> <ul style="list-style-type: none"> • Ensuring that the private sector complies with TBT standards and regulations • Making the stakeholders aware of the TBT standards and regulations • Seeking technical and financial assistance required for the implementation of TBT • Allocating the budget for the implementation of TBT 	<p>pharmaceutical product patent expires in 2016</p> <ul style="list-style-type: none"> • Bringing in force effective and strong laws that deal with IPRs such as Industrial Property, Plant Variety Protection • Seeking technology transfer and technical and financial cooperation from developed Members, which has been provisioned in Articles 66 and 67 of TRIPS • Making alliance with like-minded WTO members to make sure that TRIPS does not negatively affect public health and patent does not restrict access to medicines at affordable prices, for example, through the amendment of TRIPS Article 31 (f), as decided on 6 December 2005.

Annex 2

Issues of further consideration for Ministry of Health

Scope for Further Research	<ul style="list-style-type: none"> • Based on the priorities mentioned above in the matrix, there is a scope for further research in different issues, such as on issues concerning trade remedy measures, tariff imposition strategies on pharmaceutical products, implications of the phasing out of ODCs on pharmaceutical companies, implications of patent on access to medicines, TRIPS flexibilities/exceptions and Nepal's capacity to benefit from them, GATT exceptions and Nepal's capacity to benefit from them, FDI in the health sector and technology transfer, technical assistance for complying with WTO agreements etc.
Coordination, Cooperation and Partnership	<ul style="list-style-type: none"> • Strengthening the coordination and cooperation between different WTO cells formed within ministries. • Strengthening of coordination and cooperation between officials and secretaries of Ministry of Industry, Commerce and Supplies; Ministry of Agriculture and Cooperatives; Ministry of Finance; and Ministry of Health and Population and also between the related departments and institutions under these ministries • Providing inputs to each other's policies and laws through policy discussion programmes on issues of WTO and public health • Providing regular feedback to each other's programmes and projects concerning WTO, trade and public health through information sharing meetings • Strengthening of networking and partnership with private sector through meetings, dialogues etc. • Involving stakeholders such as civil society, media, individual experts etc. during meetings, discussions and dialogues for institutionalising participatory policymaking process
Institutional Strengthening	<ul style="list-style-type: none"> • Institutional strengthening through programmes and projects for human resources development, provisioning of libraries, division of work based on interest and expertise etc. • Planning for seeking technical and financial assistance for institutional strengthening • Ensuring alliance with other related institutions, agencies for information sharing and enhancement of knowledge and technical expertise
Law and policy making	<ul style="list-style-type: none"> • Preparing laws and policies in line with Nepal's commitments at the WTO. • Ensuring stakeholders' participation (as mentioned above) in the law and policy making process • Making an analysis of the laws and policies of other countries, such as South Asian countries to take lessons and inputs. • Informing people at large about the laws and policies through media.

Annex 3

HMG Officials and other professionals consulted during the field study

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Ms Savitri Gurung Monitoring and Evaluation Officer GTZ – Health Sector Programme Teku, Kathmandu	Mr Ram Prashad Sharma Department of Customs Tripureshwor, Kathmandu	Mr Mohan K. Maharjan Department of Food Technology and Quality Control Babar Mahal, Kathmandu
Mr Srijol Acharya Nepal Medical Council Maharajjung, Kathmandu	Mr Hari Basyal Ministry of Industry, Commerce and Supplies Singha Durbar, Kathmandu	Ms. Niru Shrestha Officer Resource Centre for Primary Health Care (RECPECH) Bagbazar, Kathmandu
Nepal Nursing Council Maharjgunj, Kathmandu	Rajiv Gurbacharya Officer American Life Insurance Company Pulchowk, Kathmandu	

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